IN THE UNITED STATES COURT OF FEDERAL CLAIMS

ACLR, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Nos. 15-767C & 16-309C
	)	(Judge Campbell-Smith)
THE UNITED STATES,	)	
	)	
Defendant.	)	

DEFENDANT'S RESPONSE TO PLAINTIFF'S
PROPOSED FINDINGS OF UNCONTROVERTED FACT AND
ADDITIONAL PROPOSED FINDINGS OF UNCONTROVERTED FACT

Pursuant to the Court's scheduling order dated February 8, 2018, defendant, the United States, submits this response to the proposed findings of uncontroverted fact submitted by plaintiff, ACLR, LLC (ACLR), along with defendant's additional proposed findings of uncontroverted fact.

RESPONSE TO PLAINTIFF'S PROPOSED FINDINGS OF UNCONTROVERTED FACT

The Part D Recovery Audit Contractor

1. CMS was required by law to establish a Part D recovery audit contract for the recovery of improper payments. Section 6411(b) of the Affordable Care Act ("ACA"); App. at Ex.1, Excerpts of deposition of Cindy Moreno ("Moreno Dep.") at 31:14-32:4; App. at Ex. 2, Excerpts of deposition of Camille Brown ("C. Brown Dep.") at 79:11-20.

RESPONSE: Admitted.

2. On December 2, 2010, CMS submitted a Request for Quote ("RFQ") to ACLR for the Recovery Audit Contractor Services in Support of Medicare Part D contract ("Part D RAC") and represented that CMS intended to award a firm-fixed price contingency fee task order for the work such that the recovery audit contractor would only be paid on a percentage of the total Part D improper payment amounts recovered from plan sponsors. App. at Ex.3, RFQ for Part D RAC.

RESPONSE: Admitted.

3. The purpose of Part D RAC was to obtain contractor support for the Center for Medicare and Medicaid Services ("CMS") in the identification of improper payments and the recoupment of overpayments in Medicare Part D. App. at Ex. 4, Statement of Objectives.

RESPONSE: Admitted.

4. The Part D RAC contractor would be responsible for the identification and recovery of improper payments on a national scale. *Id.*

RESPONSE: Qualified. Defendant agrees that the Statement of Objectives (SOO) stated that the Part D RAC contractor "shall identify and recover improper payments made under Medicare Part D." Tab 4, A31.[1] However, the parties later agreed that it would be CMS which "collects the Medicare overpayments." Tab 21, A392.

The Performance Work Statement

5. On December 14, 2010, in response to the RFQ, ACLR submitted its technical proposal and Performance Work Statement ("PWS") to CMS. App. at Ex.5, ACLR Technical Proposal.

RESPONSE: Admitted.

6. The PWS established the audit types and associated processes, including the methodologies to be used by ACLR to identify and recover Part D improper payments arising from duplicative payments, direct and indirect remuneration, and improper plan sponsor prescription drug event data submission audit issues. Id.; App. at Ex.6, Excerpts from 30(b)(6) deposition of CMS in ACLR I ("CMS 30(b)(6) Dep.") at 15:20-16:2.

RESPONSE: Denied. Defendant agrees that the Performance Work Statement (PWS), which was drafted entirely by ACLR at the time it responded to the Request for Quotes, stated that ACLR proposed conducting recovery audits focusing on duplicate payments, direct and indirect remuneration, and improper plan sponsor prescription drug event (PDE) data

[1] References to Tabs 1-75 and "A__" are to the appendix submitted with ACLR's motion for summary judgment. References to Tabs 76-142 and "SA__" are to the supplemental appendix being submitted with defendant's response and cross-motion for summary judgment.

submissions. However, ACLR did not provide CMS with the specific methodology that it proposed to use to analyze duplicate payments until September 30, 2011. That was the first time ACLR informed CMS of the specific process ACLR proposed to use for identifying potential duplicate payments within the PDE record data. Tab 5, A50, A58, A61; Tab 90, SA240-41 at 111:3-112:9; Tab 109, SA600.

The Part D RAC Contract

7. On January 13, 2011, CMS awarded Contract No. GS-23F-0074W/Task Order No. HHSM-500-2011-00006G ("Part D RAC Contract") to ACLR, which incorporated ACLR's PWS in its entirety, including a base period and four 12-month option periods to be executed at CMS's discretion. App. at Ex.7, Part D RAC Contract.

RESPONSE: Admitted.

8. The primary purpose of the Part D RAC Contract was to identify and collect improper payments. App. at Ex. 6, CMS 30(b)(6) Dep. at 14:15-18; 163:3-6; App. at Ex.8, Excerpts of deposition of Theresa Schultz ("Schultz Dep.") at 44:10-16; App. at Ex. 9, Excerpts of deposition of Nicole Hoey ("Hoey Dep.) at 110:16-18.

RESPONSE: Qualified. Defendant agrees that the purpose of the Part D RAC Contract was the identification and collection of improper payments. Although the SOO stated that the Part D RAC contractor "shall identify and recover improper payments made under Medicare Part D," the parties later agreed that it would be CMS which "collects the Medicare overpayments." Tab 4, A31; Tab 21, A392.

9. At the outset of the Part D RAC Contract, ACLR was to collect Part D overpayments. App. at Ex.7, Part D RAC Contract at section 5; App. at Ex. 6, CMS 30(b)(6) Dep. at 19:1-11; 28:4-14; App. at Ex.10, Excerpts of deposition of Tanette Downs ("Downs Dep.") at 57:9-20.

RESPONSE: Admitted.

10. Given the contingency structure of the Part D RAC Contract, if ACLR was not allowed to pursue the recovery of improper payments, ACLR would not be paid

under the Part D RAC Contract. App. at Ex.11, Excerpts of Deposition of Desiree Wheeler ("Wheeler Dep.") at 35:10-36:3.

RESPONSE: Qualified. Defendant agrees that the parties' contract only allowed ACLR to be paid in the form of a contingent fee based on amounts of overpayments actually recovered by CMS. So even if CMS approved a particular recovery audit issue, ACLR would not be paid unless overpayments actually were recouped by CMS as a result of that audit. So ACLR "being allowed to pursue" a recovery audit, by itself, would not entitle ACLR to any contingent fee payments, unless overpayments ultimately were recouped by CMS as a result of that audit. That is consistent with the underlying RAC statute, 42 U.S.C. § 1395ddd(h)(1)(A), (B). Tab 7, A159; Tab 21, A392; Tab 22, A440.

11. As of the date the Part D RAC Contract was awarded there were no rules or regulations that governed ACLR's Part D efforts. App. at Ex. 1, Moreno Dep. at 36:11-37:15.

RESPONSE: Denied. Defendant agrees that, as of the date on which the Part D RAC task order was awarded to ACLR on January 13, 2011, CMS had not issued any rules or regulations that specifically governed the operation of the Part D RAC program. However, existing statutes and guidance issued by the Office of Management and Budget (OMB) governed the operation of the Part D RAC. *See, e.g.*, 42 U.S.C. § 1395ddd(h)(1)(A), (B); Tab 18, A344; Tab 89, SA169.

12. In January 2011, CMS Director Moreno, responsible for the overall implementation of the Part D RAC program, tasked a separate contractor, Booz Allen Hamilton, Inc. ("BAH") to develop the Part D RAC program and a corresponding statement of work. See App. at Ex. 1, Moreno Dep. at 58:17-60:19.

RESPONSE: Qualified. Ms. Moreno was not the director of CMS, but rather a division director of a group within the Center for Program Integrity within CMS at the time the Part D RAC contract was issued to ACLR. The cited testimony supports the assertion that, in that role,

Ms. Moreno had oversight responsibility for the Part D RAC program and work performed by a separate contractor, Booz Allen Hamilton.

13. Moreno also determined that ACLR would be unable to recover improper payments or collect fees until the program had been implemented and made no attempt to notify ACLR that CMS would not execute the Part D RAC Contract or to modify it so that ACLR could be compensated for its work efforts prior to an implementation of the program in a manner that was satisfactory to CMS. *See* App. at Ex.1, Moreno Dep. at 69:12-71:8; 74:3-76:1; App. at Ex. 8, Schultz Dep. at 64:22-65:20; App. at Ex. 12, July 8, 2011 CMS emails.

RESPONSE: Denied. The cited testimony does not support the characterization that CMS "would not execute the Part D RAC Contract or to modify it so that ACLR could be compensated for its work efforts prior to an implementation of the program in a manner that was satisfactory to CMS." For instance, the cited deposition testimony from Ms. Schultz states only that she believed that, if an audit issue proposed by ACLR was "not valid, the audit cannot proceed" under the terms of the parties' contract. The cited testimony states that Ms. Moreno did not notify others within CMS that any modification to ACLR's contract should be pursued to provide compensation for ACLR on other than a contingent fee basis, but does not support the characterization that ACLR actually was entitled to any such modification or compensation under governing law.

14. During 2011, CMS did not meet PWS requirements to establish a data store and did not complete the security audits necessary for ACLR to timely receive and commence reviewing Part D prescription drug events ("PDEs"). App. at Ex.13, Excerpts of Deposition of Marnie Dorsey ("Dorsey Dep.") at 29:5-10; 109:3-22; App. at Ex.7, Part D RAC Contract; App. at Ex. 14, October 7, 2011 Authorization Decision.

RESPONSE: Denied. Defendant agrees that CMS did not establish a data store from which ACLR could access PDE records, instead developing a process through which PDE records could be transmitted to ACLR for review. Under the contract, it was ACLR's deliverable to obtain its IT security classification and accreditation in order to receive access to

CMS's PDE records. The timeline contained in the PWS, drafted by ACLR, stated only that ACLR's systems security officer would "coordinate with CMS to develop/clarify system security level requirements" within three months of contract award. Neither the task order nor ACLR's PWS imposed any deadline on CMS to verify ACLR's IT system security capabilities or to issue an authority to operate. The cited deposition testimony does not support the characterization that "CMS did not meet PWS requirements." Tab 7, A212.

15. CMS also ignored PWS appeal processes and Part D RAC task order requirements regarding ACLR's collection of improper payments. App. at Ex. 6, CMS 30(b)(6) Dep. at 40:20-42:15; App. at Ex. 10, Downs Dep. at 124:8-17; App. at Ex. 7, Part D RAC Contract at section 5.

RESPONSE: Denied. The cited deposition testimony supports the assertion that the appeals process, as drafted by ACLR in the PWS, was not the appeals process that CMS ultimately employed under the Part D RAC program. However, ACLR agreed near the outset of the contract, before it had undertaken any recovery audits, that only the portions of the PWS that CMS agreed to implement would apply while the parties drafted, revised, and implemented an updated Statement of Work (SOW). The appeals process followed by CMS was as defined in the SOW. Tab 21, A404, A417-420; Tab 22, A439, A454-461; Tab 110, SA602.

16. CMS acknowledged that it did not follow PWS requirements. App. at Ex.13, Dorsey Dep. at 132:20-135:7; App. at Ex.15, GAO Report "MEDICARE PART D: Changes Needed to Improve CMS's Recovery Audit Program Operations and Contractor Oversight" ("GAO Report") at page 17; App. at Ex.16, December 17, 2013 CMS email; App. at Ex.17, December 2014 emails.

RESPONSE: Denied. Defendant agrees that CMS communicated to ACLR in November 2011 that CMS did not want ACLR to begin issuing repayment notification letters to plan sponsors on an audit issue that had never been reviewed or analyzed by CMS, and that CMS wanted to replace the PWS with an updated SOW that would accurately reflect ACLR's expected performance as the Part D RAC. ACLR agreed that only the portions of the PWS that

CMS agreed to implement would apply while the parties drafted, revised, and implemented an updated SOW. While the SOW was being drafted and revised, the parties agreed that ACLR would only perform specific audit issues that were authorized by CMS through contract modifications. Tab 28, A513; Tab 36, A553; Tab 78, SA114; Tab 79, SA116; Tab 110, SA602.

17. Former Part D Part D RAC Contracting Officer Schultz acknowledged that CMS did not act in accordance with PWS requirements and testified that CMS "had a contract with the PWS in it that we weren't agreeing with . . . . which is why we were doing the statement of work." App. at Ex. 8, Schultz Dep. at 151:10-22.

RESPONSE: Denied. Defendant agrees that CMS communicated to ACLR in November 2011 that CMS did not want ACLR to begin issuing repayment notification letters to plan sponsors on an audit issue that had never been reviewed or analyzed by CMS, and that CMS wanted to replace the PWS with an updated SOW that would accurately reflect ACLR's expected performance as the Part D RAC. ACLR agreed that only the portions of the PWS that CMS agreed to implement would apply while the parties drafted, revised, and implemented an updated SOW. While the SOW was being drafted and revised, the parties agreed that ACLR would only perform specific audit issues that were authorized by CMS through contract modifications. Tab 28, A513; Tab 36, A553; Tab 78, SA114; Tab 79, SA116; Tab 110, SA602.

18. In a GAO report, GAO stated that "CMS officials said they proposed that the RAC perform work and follow processes that were not in the performance work statement . . . ." App. at Ex.15, GAO Report at page 17.

RESPONSE: Qualified. The full sentence in the GAO report states, "CMS officials said they proposed that the RAC perform work and follow processes that were not in the performance work statement *because they recognized during the first year of the contract that the RAC had less expertise in Medicare Part D regulations and the Part D benefit than was necessary*." Tab 15, A312 (emphasis added).

Calculation of Part D Payments & Improper Payment Determination

19. Plan sponsors must also certify that their Part D PDE claim submissions are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining federal reimbursement and are in compliance with Health Insurance Portability & Accountability Act ("HIPAA") simplification rules. 42 CFR 423.505(k)(3); 42 CFR 423.505(h)(2).

RESPONSE: Defendant objects on the ground that this paragraph is a conclusion of law, not a statement of proposed fact. To the extent a response is required, defendant agrees with ACLR's summary of the cited regulations.

20. The Office of Management & Budget ("OMB"), responsible for establishing improper payment guidance, defines an improper payment as:

> An improper payment is any payment that should not have been made or that was made in an incorrect amount under statutory, contractual, administrative, or other legally applicable requirements. Incorrect amounts are overpayments and underpayments (including inappropriate denials of payment or service). An improper payment includes any payment that was made to an ineligible recipient or for an ineligible service, duplicate payments, payments for services not received, and payments that are for the incorrect amount. In addition, when an agency's review is unable to discern whether a payment was proper as a result of insufficient or lack of documentation, this payment must also be considered an error.

App. at Ex.18, excerpts of Part III to OMB Circular A-123, Appendix C.

RESPONSE: Admitted.

21. The OMB definition of an improper payment was included in the Part D RAC Contract PWS and was the improper payment definition used by CMS. App. at Ex. 7, Part D RAC Contract, PWS at 38; App. at Ex. 6, CMS 30(b)(6) dep. at 56:21-57:8; 84:3-85:20; App. at Ex.19, CMS Part D RAC Overview at page 21.

RESPONSE: Admitted.

22. ACLR reviews final reconciliation PDEs to make determinations of payment veracity and to identify and recover Part D improper payments. App. at Ex. 20, Affidavit of Christopher Mucke in Support of Motion for Partial Summary Judgment ("Mucke Aff.") at ¶ 13.

RESPONSE: Qualified. Defendant agrees that, while the Part D RAC Contract was in effect, ACLR was tasked with reviewing reconciled PDE records to identify Part D improper payments. Specifically, as the Part D RAC, ACLR was tasked with "identifying past improper payments in reconciled Medicare PDE claims and providing information to CMS to help prevent future improper payments." Tab 21, A398; Tab 22, A433.

23. ACLR is not responsible for reviewing any PDE changes occurring after final reconciliation as this information constitutes "new payment information" that would only be included in any "subsequent reopening of the final reconciliation." App. at Ex. 21, Part D RAC Contract, OY1 SOW, Appendix C; App. at Ex. 22, OY2 SOW, Appendix C; See App. at Ex. 23, October 4, 2011 email.

RESPONSE: Qualified. Defendant agrees that ACLR, as the Part D RAC, was tasked with analyzing and reviewing reconciled PDE records, and that the appeals policy contained in the contract SOW states that PDEs submitted by the plan sponsor subsequent to the final reconciliation of the plan year being reviewed, constitute new payment information, and were not considered by the RAC as part of its review and have no relation to the RAC findings. This new information will not be considered in this appeals process, but will be included in any subsequent reopening of the final reconciliation for the plan year." Tab 21, A418; Tab 22, A455.

24. CMS began transmitting Part D payment data to ACLR on November 17, 2011, 200 days past PWS requirements. App. at Ex. 6, CMS 30(b)(6) Dep. at 49:11-52:7; App. at Ex. 13, Dorsey Dep. at 109:3-7, 109:10-22; App. at Ex. 24, November 2011 email thread.

RESPONSE: Denied. Defendant agrees that CMS began transmitting Part D PDE data to ACLR on November 17, 2011. However, none of the record citations support the characterization that CMS's transmittal of that data was "200 days past PWS requirements." On the contrary, the PWS did not contain any deadline for CMS to provide PDE data to ACLR, only

a timeline in which ACLR's own systems security officer was expected to consult with CMS about systems security requirements. Tab 7, A212.

25. The Part D RAC Contract PWS authorized ACLR's recovery of duplicate payments. App. at Ex. 7, Part D RAC Contract, PWS at 36; App. at Ex. 6, CMS 30(b)(6) Dep. at 57:9-58:6; [sic]

RESPONSE: Denied. Defendant agrees that ACLR's PWS stated that one of the recovery audit issues that it proposed to examine involved potential duplicate payments. The PWS did not specifically authorize ACLR to pursue that or any other audit issue, and ACLR agreed not to perform under the PWS, except to the extent authorized by CMS, while the parties drafted, revised, and implemented an updated SOW to replace the PWS. Tab 110, SA602.

26. One of the primary focuses of ACLR's review under the Part D RAC Contract was the duplicate payment review. App. at Ex. 6, CMS 30(b)(6) Dep. at 55:11-20.

RESPONSE: Denied. Defendant agrees that ACLR's PWS stated that one of the recovery audit issues that it proposed to examine involved potential duplicate payments. The PWS did not specifically authorize ACLR to pursue that or any other audit issue, and ACLR agreed not to perform under the PWS, except to the extent authorized by CMS, while the parties drafted, revised, and implemented an updated SOW to replace the PWS. Tab 110, SA602.

27. In addition to its approval of duplicate payment recoveries in the PWS, CMS separately approved the duplicate payment audit issue. App. at Ex. 6, CMS 30(b)(6) Dep. at 174:13-176:4; App. at Ex. 23, October 4, 2011 email; App. at Ex.10, Downs Dep. at 76:12-77:12; App. at Ex. 19, CMS Part D RAC Overview at page 9.

RESPONSE: Denied. CMS did not approve any specific duplicate payment audit through the incorporation of ACLR's PWS into the initial task order, it only approved of the concept of ACLR pursuing potential recovery audits involving duplicate payments. Subsequently, CMS did approve ACLR's proposed recovery audit involving 2010-2012 potential

duplicate payments. Approval for that audit issue later was rescinded. Tab 112, SA606; Tab 59, A656.

28. To conduct the plan year 2007 duplicate payment audit, ACLR relied on plan sponsor certifications that PDE records had been accurate, complete, and truthful and that the data were in compliance with HIPAA simplification rules and matched PDE records containing the same HICN, SRN, pharmacy, and fill number to identify individual prescriptions and eliminate duplicates arising from permissible dosage changes by contract. App. at Ex. 20, Mucke Aff. at ¶ 19. ACLR did not include duplicates arising from PDE records where the fill number was equal to zero. *Id.*

RESPONSE: Qualified. Defendant agrees that ACLR attempted to identify potential duplicate payments within the 2007 PDE data by looking for PDE records containing the same HICN, SRN, pharmacy, and fill number, and that ACLR stated that it did not include duplicates arising from PDE records where the fill number was equal to zero. ACLR did not provide copies of the 2007 PDEs that it identified using that protocol to CMS at the time that ACLR proposed issuing overpayment demand letters to plan sponsors in November 2011. Tab 90, SA244-45 at 118:21-119:15, SA256-57 at 154:22-155:9, SA286-88 at 288:5-290:13.

29. To eliminate permissible partial fills, ACLR reviewed the dispensing status field on each PDE to determine whether duplicative fill numbers arose as the result of a partial fill and eliminated those partial fills from further review. *Id.* at ¶ 20.

RESPONSE: Admitted.

30. Upon elimination of permissible partial fills, ACLR sorted the remaining prescriptions by the date the PDE was filled by the pharmacy ("Date of Service") and identified the earliest PDE Date of Service as the original payment and subsequent PDEs with the same Date of Service as duplicate improper payments. *Id.* at ¶ 21.

RESPONSE: Admitted.

31. Using this methodology, ACLR identified plan year 2007 Part D duplicate payment amounts totaling $313,808,241. *Id.* at ¶ 22.

RESPONSE: Qualified. Defendant agrees that ACLR contends that it identified $313,808,241 in potential duplicate payments for 2007 PDE records, and that ACLR informed CMS of that total sum. However, ACLR's findings were never validated, nor were ACLR's results communicated to plan sponsors to allow plan sponsors to submit evidence to rebut ACLR's contentions that the specific PDEs were, in fact, duplicates. Tab 90, SA245 at 119:7-15; Tab 106, SA481.

32. As of November 3, 2011, ACLR's duplicate payment audit methodology was technically acceptable. App. at Ex. 1, Moreno Dep. at 87:1-8; App. at Ex. 25, November 3, 2011 email at page 8.

RESPONSE: Qualified. Defendant agrees that, as of November 3, 2011, CMS had deemed ACLR's proposed methodology for identifying potential duplicate payments to be technically acceptable, given what CMS knew at that time. However, the parties' subsequent attempts to complete the 2010-2012 duplicate payment audit issue and the data validator Livanta's analysis concerning ACLR's methodology revealed additional concerns. Tab 113, SA611-12; Tab 114, SA619-20; Tab 56, A643; Tab 117, SA626; Tab 118, SA628-29.

33. In a November 30, 2011 conference call, ACLR Managing Principal Christopher Mucke, notified CMS Contracting Officer ("CO") Wheeler and CMS Program Integrity Director Downs that ACLR would commence issuing notification of improper payment letters ("NIPs") to plan sponsors and begin recouping amounts associated with 2007 Part D duplicate payments in accordance with the PWS. App. at Ex. 10, Downs Dep. at 56:13-57:8.

RESPONSE: Admitted.

34. During this call, CMS Contracting Officer Representative ("COR") Dorsey told ACLR her position that the PWS was simply a proposal and was not approved by CMS. App. at Ex. 13, Dorsey Dep. at 133:4-15; 134:12-19; 135:3-7; 181:4-182:5.

RESPONSE: Admitted.

35. CO Wheeler advised ACLR to not issue the NIP demand letters to recover PY 2007 duplicate payments. App. at Ex. 11, Wheeler Dep. at 86:6-88:11; 89:13-18; 100:10-21; App. at Ex. 10, Downs Dep. at 58:7-10.

RESPONSE: Admitted.

36. While the Part D RAC Contract required that ACLR collect Part D overpayments, ACLR was directed to not pursue its recovery efforts for 2007 duplicate payments, in part, because CMS had not developed its preferred payment collection processes. App. at Ex. 7, Part D RAC Contract at section 5; App. at Ex. 6, CMS 30(b)(6) Dep. at 58:7-13; 176:4-6; App. at Ex. 10, Downs Dep. 56:13-57:8; 58:11-59:5; 128:15-18.

RESPONSE: Denied. The cited deposition testimony does not support the proposed assertion that the PWS "required" that ACLR, rather than CMS, collect any identified overpayments. Defendant agrees that the PWS stated that ACLR would collect identified overpayments, and that CMS informed ACLR at the time of the November 30, 2011, conference call that CMS had not yet implemented a mechanism by which Part D overpayments could be collected or recouped, so that it would be premature for ACLR to commence sending overpayment notices to plan sponsors based on alleged 2007 duplicate payments.

37. For CMS to instruct ACLR to take action inconsistent with the Part D RAC Contract, CMS should have followed-up immediately with a contractual document. App. at Ex. 11, Wheeler Dep. at 72:6-73:4.

RESPONSE: Defendant objects on the ground that this paragraph is a conclusion of law, not a statement of proposed fact. To the extent a response is required, denied. The cited deposition testimony does not support the proposed fact. Ms. Wheeler actually testified that *if* CMS instructed a contractor not to follow a provision contained in a contract, her expectation would be to "follow up immediately with a contractual document," which she testified did not mean within any particular timeline, and that "if it's something that you agree to with the contractor and as long as you have verbal agreement . . . then as long as you have [] agreement then you should do it as soon as possible." Tab 11, A266-67 at 72:3-73:15.

38. ACLR's 7.5% contingency fees on $313,808,241 of plan year 2007 duplicate payments amounts to a contingency fee payment under the Part D RAC Contract of $23,628,892. App. at Ex. 7, Part D RAC Contract at section 2.

RESPONSE: Denied. 7.5% of $313,808,241 does not equal $23,628,892. Moreover, the parties' contract only allows for payment of contingency fees to ACLR based off of overpayments actually recouped by CMS, not based on potential overpayments identified by ACLR but not recouped. Tab 21, A392; Tab 91, SA299 at 39:18-22, SA302 at 59:11-22.

39. On December 9, 2011, CMS submitted a draft statement of work to ACLR, which outlined a revised Part D RAC recovery processes. App. at Ex. 26, December 9, 2011 email.

RESPONSE: Admitted.

40. After some revisions, ACLR's approval of the statement of work was communicated to CMS on April 20, 2012. App. at Ex. 6, CMS 30(b)(6) Dep. at 114:10-22; App. at Ex. 27, April 20, 2012 email approving draft SOW.

RESPONSE: Admitted.

41. In early 2012, CMS refused to allow ACLR to conduct a PY 2007 duplicate payments audit special study similar to that approved for the PY 2007 excluded provider audit. App. at Ex. 20, Mucke Aff. at ¶ 23.

RESPONSE: Denied. Defendant agrees that CMS did not permit ACLR to pursue a recovery audit of potential 2007 duplicate payments, as explained during the November 30, 2011, telephone conference. However, paragraph 23 of the cited affidavit does not support the assertion that CMS communicated a denial of any request by ACLR to perform such an audit "in early 2012."

42. On November 13, 2013, ACLR submitted improper payments to CMS totaling $1.05 billion and informed CMS that ACLR would commence recoveries in accordance with its PWS. App. at Ex. 43, November 17, 2013 email. However, CO Hoey directed ACLR to not send NIP demand letters to plan sponsors. App. at Ex. 44, November 22, 2013 email.

RESPONSE: Denied. Defendant agrees that, on November 17, 2013, ACLR sent an email to CMS in which ACLR asserted that it had identified $1.05 billion in alleged improper payments, and that ACLR intended to begin sending improper payment notifications to plan sponsors related to those amounts six days later. The cited document does not support the assertion that ACLR had "submitted improper payments to CMS totaling $1.05 billion," only that ACLR had communicated to CMS that ACLR had identified those amounts and intended to commence recovery of those amounts from plan sponsors. Tab 44, A581-82.

Option Year 1 Statement of Work

43. On December 31, 2013, CMS executed Modification 13 to the Part D RAC ("OY1 SOW"), which replaced the PWS with a statement of work containing, among other things, a New Audit Issue Review Package ("NAIRP") process for submitting improper payment audit issues for CMS review and approval and an Improper Payment Review Package ("IPRP") process used by ACLR to submit improper payment PDEs from approved NAIRPs via CMS's payment recovery information system to a data validation contractor ("DVC") responsible for validating ACLR findings in accordance with the approved NAIRP audit methodology. App. at Ex. 21, Part D RAC Contract, OY1 SOW; App. at Ex. 8, Schultz Dep. at 33:19-34:2.

RESPONSE: Admitted.

44. The OY1 SOW also contained contingency fee payments for new approved issues of 15% for up to $10 million in recoveries and 12% thereafter. App. at Ex. 21, Part D RAC Contract, OY1 SOW.

RESPONSE: Qualified. Defendant agrees that the SOW provided for contingency fee payments to ACLR in the amount of 15% of *recoveries* for the first $10 million recovered, and 12% of *recoveries* for any additional amounts recovered, for any subsequently approved audit issues. The SOW did not provide for contingency fee payments for new audit approved issues unless those approved audit issues resulted in recoupment of overpayments by CMS. Tab 21, A392.

45. At the request of ACLR, the OY1 SOW also incorporated a Part D RAC Activities Timeline, Appendix E, to provide individual tasks, deadlines and responsible parties for "New Issues Submission and Approval Process," and the complex and automated review processes and procedures from initial IPRP submission through RAC payment. App. at Ex. 21, OY1 SOW at Appendix E; App. at Ex. 9, Hoey Dep at 29:20-32:14.

RESPONSE: Qualified. Defendant agrees that the SOW contained a timeline for the NAIRP approval process and subsequent recovery audit activities. However, the cited testimony from Ms. Hoey also states that the timeline was intended to be a "sample timeline" for which the agency "tried to meet the deadlines." Tab 9, A241 at 32:4-9.

46. By the time OY1 SOW was executed on December 31, 2013, almost six years had passed since the conclusion of PY 2007 and the window had expired for ACLR to pursue the plan year 2007 duplicate payments under the new framework of the OY1 SOW because of statute of limitation periods and appeal timeline constraints. App. at Ex. 10, Downs Dep. at 74:5-17; App. at Ex. 6, CMS 30(b)(6) Dep. at 199:6-15.

RESPONSE: Defendant objects on the ground that this paragraph is a conclusion of law, not a statement of proposed fact. To the extent a response is required, qualified. Defendant agrees that, as of the incorporation of the SOW on December 31, 2013, the limitations period had expired for any efforts by CMS to recoup overpayments occurring in the 2007 PDE data. However, nothing in the cited testimony supports the inference made by ACLR that it ever had proposed to pursue a recovery audit for potential duplicate payments within the 2007 PDE data after the November 30, 2011, conference call with CMS.

Plan Year 2010 Duplicate Payments

47. On January 2, 2014, ACLR submitted its NAIRP for plan year 2009-2012 duplicate payments. App. at Ex. 20, Mucke Aff. at ¶ 27.

RESPONSE: Admitted.

48. After multiple revisions, which also eliminated a review of the 2009 plan year, CMS approved ACLR's review of 2010-2012 duplicate payments NAIRP on May

28, 2014 - 42 days after contracted deadlines. App. at Ex. 6, CMS 30(b)(6) Dep. at 224:2-225:2; App. at Ex. 45, May 28, 2014 revised NAIRP approval.

RESPONSE: Denied. Defendant agrees that CMS issued notice to ACLR that CMS had approved ACLR's 2010-2012 duplicate payment NAIRP on May 28, 2014. However, nothing in the cited references supports ACLR's assertion that CMS's decision was issued "42 days after contracted deadlines." On the contrary, ACLR's proposed 2010-2012 duplicate payment audit issue had been revised multiple times over many months, demonstrating the iterative process of getting proposed recovery audit issues reviewed and approved. Tab 107, SA492.

49. Under the approved methodology in the NAIRP, ACLR identified duplicate payments using CMS's Uniform Examination Program ("UEP") duplicate payment protocol whereby potential duplicate payments are identified as "PDEs submitted to the same beneficiary, for the same medication, and on the same/very close dates." App. at Ex. 20, Mucke Aff. at ¶ 28. To match individual PDE fields, ACLR matched PDE records containing the same contract and prescription drug plan, HICN, NDC, and fill number fields. *Id.* at ¶ 29.

RESPONSE: Qualified. Defendant agrees that ACLR employed the described process to attempt to identify potential duplicate payments, but as ACLR acknowledged, the PDE records that it identified using that process were only potential duplicate payments which would require further examination of supporting documentation submitted by plan sponsors. Tab 107, SA493-94.

50. To determine the "same/very close dates," the NAIRP contained an early refill methodology, which consisted of comparing the days' supply of the originating PDE record to the days elapsed between the originating PDE and subsequent matching PDE record and calculating the days between each PDE's respective Date of Service. *Id.* at ¶ 30. Potential duplicate payments were identified when the days elapsed were less than 50% of the days' supply of the originating PDE record. *Id.*

RESPONSE: Admitted.

51. The approved NAIRP audit methodology precluded the review of PDEs associated with long term care facilities and mail order pharmacies and these records were eliminated from ACLR's audit. *Id.* at ¶ 31.

RESPONSE: Qualified. Defendant agrees that the approved NAIRP audit methodology precluded ACLR from identifying as potential duplicate payments prescriptions associated with long term care facilities and mail order pharmacies. However, the data validator, Livanta, reported to CMS that the PDE records identified by ACLR actually included prescriptions involving long term care facilities and mail order pharmacies. Tab 113, SA612.

52. The NAIRP also required that the audit be conducted as a complex review, which required that ACLR obtain evidentiary support such as copies of prescriptions and prescription fill histories for improper payment PDEs via a Request for Information ("RFI") to plan sponsors. App. at Ex. 46, May 6, 2014 email; App. at Ex.47, RFI letter.

RESPONSE: Admitted.

53. After ACLR had completed its initial audit and was preparing to issue RFIs to plan sponsors, CMS, noting that "this piece of the process is not in the current contract," informed ACLR that it could not send RFIs to plan sponsors until the DVC, using "the approved methodology," had reviewed the RFIs and that the DVC's validation process "should be no longer than a week." App. at Ex.48, June 2014 email thread; See App. at Ex. 49, Excerpts of the deposition of Sonja Brown ("S. Brown Dep.") at 34:21-35:15.

RESPONSE: Qualified. Defendant agrees that CMS informed ACLR that the data validator, Livanta, would review ACLR's PE results to validate ACLR's compliance with the approved methodology for conducting the 2010-2012 duplicate payment audit issue. ACLR also informed CMS that it "recognize[d] the authority of CPI, under Appendix E . . . to dictate the terms of the actual approval." Tab 48, A594.

54. ACLR submitted its RFI findings to CMS on June 10, 2014. App. at Ex. 20, Mucke Aff. at ¶ 32.

RESPONSE: Admitted.

55. On June 25, 2014, the DVC found that ACLR's PY 2010-2012 duplicate payment RFIs only generated 0.0065 in false positives. App. at Ex. 50, October 2014 email thread.

RESPONSE: Denied. Livanta's analysis was that ACLR had an error rate – not a false positive rate – of .65%. As Livanta's analysis shows, all that the error rate signified was that ACLR's report of PDEs containing potential duplicate payments "correctly applied the approved methodology" except in .65% of the claims. Whether ACLR's methodology was likely to capture false positives was a separate issue, which Livanta determined would occur in 56% of the PDEs found by ACLR. Tab 50 at A611; Tab 113, SA610.

56. In addition to its validation work for the Duplicate Payment RFI Report, the DVC deviated from the methodology approved in the NAIRP and applied a "dosage increase" percentage to identify possible permissible dosage changes. See App. at Ex. 51, Duplicate Payment Report; App. at Ex. 20, Mucke Aff. at ¶ 33.

RESPONSE: Denied. Defendant agrees that Livanta's validation process examined, among other things, whether the PDEs identified by ACLR reflected a dosage increase between the multiple prescriptions identified as duplicates by ACLR. Livanta's analysis was not a "deviation" from the duplicate payment audit issue methodology, but rather one component of an effort to identify and exclude from ACLR's results PDEs that were likely false positives, because they did not reflect duplicate prescriptions at all. Livanta's analysis was that 56% of the prescriptions identified by ACLR as potential duplicates involved a dosage increase of at least 50% from the first prescription to the alleged duplicate prescription. Tab 113, SA612.

57. By applying a revised methodology that was not part of the approved NAIRP, the DVC reviewed PDE data fields not contained within CMS data submissions to ACLR for the 2011 and 2012 plan years duplicate payment audit causing CMS to only approve the release of plan year 2010 duplicate payment RFIs. App. at Ex. 20, Mucke Aff. at ¶ 34; *See* App. at Ex. 52, July 8, 2014 email.

RESPONSE: Denied. Defendant agrees that CMS only approved the release of requests for information by ACLR to plan sponsors for the duplicate payment NAIRP for 2010, not 2011 and 2012. However, CMS asked ACLR whether ACLR wanted to proceed by issuing requests for information to plan sponsors only for 2010, or if ACLR wanted to defer doing so until the

2011 and 2012 data was corrected to address dosage changes. ACLR chose to proceed with 2010 alone. Tab 52, A618.

58. On July 8, 2014, ACLR submitted the RFIs for improper 2010 duplicate payments to plan sponsors requiring, in accordance with the OY1 SOW, that evidentiary support be submitted within 60 days. App. at Ex. 20, Mucke Aff. at ¶ 35.

RESPONSE: Admitted.

59. CMS unilaterally extended the evidentiary support deadline for plan sponsors an additional 60 days. App. at Ex. 6, CMS 30(b)(6) Dep. at 209:1-11; App. at Ex. 53, October 1, 2014 CMS email extension.

RESPONSE: Denied. Defendant agrees that CMS extended the deadline for plan sponsors to respond to ACLR's request for information concerning the 2010 duplicate payment audit issue. CMS did not "unilaterally" extend that deadline, however, but did so after extensive communications with plan sponsors concerning the difficulties in responding to ACLR's request for information and the likelihood that the PDEs for which ACLR sought information were not duplicate payments at all. Tab 114, SA619-20; Tab 119, SA630.

60. CMS's extension to the plan sponsors was inconsistent with the timeline set forth in the OY1 SOW. App. at Ex. 6, CMS 30(b)(6) Dep. at 209:12-210:1.

RESPONSE: Denied. Defendant agrees that the timeline contained in Appendix E of the SOW stated that plan sponsors would have 60 days to respond to a request for information or 90 days if prescriptions were requested, and that extending the deadline to respond to ACLR's request for information provided the plan sponsors more time than specified in Appendix E. However, the cited deposition testimony states that CMS had "discretion to extend the timeline," so granting an extension was not "inconsistent" with the SOW. Tab 6, A144 at 209:12-19.

61. Ms. Sonja Brown was assigned as the COR on October 1, 2012 and was advised that she was not authorized to direct ACLR "in any way that could change the terms and conditions of the contractual instrument." App. at Ex. 54, Part D RAC Contract, Modification 5; App. at Ex. 55, Memorandum appointing COR Brown at page 2.

RESPONSE: Denied. Defendant agrees that the memorandum appointing Ms. Brown as the contracting officer's representative stated that Ms. Brown did not have authority to "change the terms and conditions of the contractual instrument." However, the memorandum also gave Ms. Brown authority to "act on behalf of the Contracting Officer with respect to technical and administrative matters, within the scope of the contract." Tab 55, A631-32.

62. On October 22, 2014, CMS instructed ACLR to apply a revised CMS methodology, based on its interpretation of the DVC report, to the 2010 duplicate payment RFI PDEs to eliminate possible permissible dosage changes and to submit new RFI IPRPs to CMS for subsequent resubmission to plan sponsors. App. at Ex. 6, CMS 30(b)(6) Dep. at 236:6-20; App. at Ex. 56, October 22, 2014 email regarding PDE adjustments; App. at Ex. 20, Mucke Aff. at ¶ 36.

RESPONSE: Admitted.

63. On December 24, 2014, after completing its review of evidentiary support submitted in response to the RFIs, ACLR submitted IPRPs to CMS for improper plan year 2010 duplicate payment amounts totaling $15,909,552, in accordance with OY1 SOW requirements. App. at Ex. 57, December 24, 2014 letter; App. at Ex. 20, Mucke Aff. at ¶ 38.

RESPONSE: Admitted.

64. Contractual language associated with approved audit issues remained unchanged with the exercising of the second option period of the Part D RAC Contract ("OY2 SOW") on December 31, 2014. App. at Ex. 21, Part D RAC Contract OY1 SOW; App. at Ex. 22, Part D RAC Contract, OY2 SOW.

RESPONSE: Defendant objects on the ground that this proposed uncontroverted fact is vague, in that it is unclear precisely what "[c]ontractual language associated with approved audit issues" ACLR is referencing, as virtually all of the SOW amounts to "[c]ontractual language associated with approved audit issues." To the extent a response is required, qualified. Defendant agrees that the only substantive changes contained in the revised SOW dated December 31, 2014, that went into effect as of January 1, 2015, related to changes made to the appeals process. Tab 22, A439, A488-51, A454-61, A465-69.

65. On January 8, 2015, ACLR was directed by CMS to resubmit ACLR's IPRPs in accordance with CMS's revised methodology. App. at Ex. 58, January 8, 2015 email.

RESPONSE: Denied. The cited document stated that CMS asked ACLR to provide the requested information to the data validator, Livanta, to address the concerns raised by Livanta regarding ACLR's duplicate payment data submission. Tab 58, A652-53.

66. Based upon ACLR's belief that CMS's direction was an additional Part D RAC Contract deviation, ACLR referred the matter to CO Hoey. App. at Ex. 20, Mucke Aff. at ¶ 37.

RESPONSE: Qualified. Defendant agrees that ACLR refused to comply with CMS's request or to provide any further information to the data validator, Livanta, concerning the 2010 duplicate payment audit issue, and instead told CMS to discuss the matter with its own contracting officer. Tab 58, A652; Tab 90, SA274-75 at 255:19-256:5.

67. On April 24, 2015, COR Brown terminated the 2010 duplicate payment audit through a "Technical Direction Letter." App. at Ex. 59, April 24, 2015 email.

RESPONSE: Qualified. Defendant agrees that on April 24, 2015, contracting officer's representative Sonja Brown issued a technical direction letter to ACLR that rescinded (rather than terminated) approval for the 2010-2012 duplicate payment audit issue. Tab 59, A657.

68. The justification for terminating the 2010 duplicate payment audit was that "although the revised methodology used by CMS was able to reduce the number of PDE records identified as improper submissions, CMS continued to have concerns with the validity of overall results." *Id.*; *See* App. at Ex. 6, CMS 30(b)(6) Dep. at 237:19-238:16.

RESPONSE: Qualified. Defendant agrees that CMS rescinded (rather than terminated) approval for the 2010-2012 duplicate payment audit issue in part because "CMS continued to have concerns with the validity of overall results." The letter further stated that plan sponsors had contacted CMS with concerns regarding the burden of providing supporting documents for what the plan sponsors believed were large numbers of PDE records that were not duplicate

payments. The letter also referenced the analysis undertaken by CMS and Livanta that concluded that there were significant flaws in the methodology being used for the audit issue, and that ACLR had refused to apply the modified methodology requested by CMS on October 22, 2014. Tab 59, A657.

69. There was no language in the Part D RAC Contract that allowed CMS to terminate an approved audit. App. at Ex. 6, CMS 30(b)(6) at 248:18-250:22; App. at Ex. 60, December 11, 2014 email regarding potential SOW changes.

RESPONSE: Defendant objects on the ground that this paragraph is a conclusion of law, not a statement of proposed fact. To the extent a response is required, denied. The deposition testimony and exhibit cited in support of this proposed uncontroverted fact do not support the assertion that CMS was not allowed under the contract to terminate or rescind a previously approved audit issue. Those exhibits reference work undertaken by CMS to propose modifications to the SOW to address other concerns unrelated to the issue of terminating or rescinding a previously approved audit issue. Indeed, ACLR previously acknowledged CMS's authority to "dictate" the methodology it wanted ACLR to use on any given audit issue and to restrict ACLR from pursuing the 2011-2012 portion of the previously approved 2010-2012 duplicate payment audit issue. Tab 90, SA262-64 at 189:20-191:10; Tab 48, A594.

70. There was no language in the Part D RAC Contract that allowed CMS to apply a revised methodology to perform 2010 duplicate payment reviews. *See* App. at Ex. 6, CMS 30(b)(6) Dep. at 173:3-174:9; 249:13-250:22.

RESPONSE: Defendant objects on the ground that this paragraph is a conclusion of law, not a statement of proposed fact. To the extent a response is required, denied. ACLR agreed on multiple occasions to modify the methodology of ACLR's proposed 2010-2012 duplicate payment audit issue up through the time of approval. ACLR also acknowledged CMS's authority to "dictate" the methodology it wanted ACLR to use on any given audit issue and to

restrict ACLR from pursuing the 2011-2012 portion of the previously approved 2010-2012 duplicate payment audit issue. Tab 90, SA262-64 at 189:20-191:10; Tab 48, A594; Tab 107, SA493.

71. ACLR's contingency fee payment for the $15,909,552 plan year 2010 duplicate payments identified by ACLR was $2,209,146. App. at Ex. 20, Mucke Aff. at ¶ 38.

RESPONSE: Denied. Defendant agrees as to the mathematical calculation performed by ACLR, that 15% of $10 million and 12% of the remaining $5,909,552 amounts to $2,209,146. However, the parties' contract only allows for payment of contingency fees to ACLR based off of overpayments actually recouped by CMS, not based on potential overpayments identified by ACLR but not recouped. Tab 21, A392; Tab 91, SA299 at 39:18-22, SA302 at 59:11-22.

Option Year 2 Statement of Work

72. On December 31, 2014, the OY2 SOW was executed under Modification 16. App. at Ex. 22, Part D RAC Contract, OY2 SOW.

RESPONSE: Admitted.

73. OY2 SOW language pertaining to CMS's promulgation that PDEs submitted by the plan sponsor subsequent to the final reconciliation of the plan year being reviewed constituted new payment information remained unchanged from the OY1 SOW and CMS's prior determination. Id. at Appendix C; App. at Ex. 23, October 4, 2011 email.

RESPONSE: Defendant objects on the ground that this proposed uncontroverted fact is vague, in that it is unclear precisely what "language pertaining to CMS's promulgation that PDEs submitted by the plan sponsor subsequent to the final reconciliation of the plan year being reviewed constituted new payment information" ACLR is referencing. To the extent a response is required, qualified. Defendant agrees that, under the revised SOW dated December 31, 2014, and incorporated into ACLR's task order as modification 16, ACLR continued to be tasked with reviewing and analyzing reconciled PDE records. Tab 22, A455.

ACLR's Sales Tax NAIRP Submission

74. The PDE record contains three detailed cost fields: ingredient cost paid, dispensing fee paid, and total amount attributed to sales tax. App. at Ex. 74, Excerpts of 2007 Prescription Drug Event Data Training Participant Guide; App. at Ex. 20, Mucke Aff. at ¶ 39.

RESPONSE: Qualified. Defendant agrees that PDE records contain fields captioned for ingredient cost paid, dispensing fee paid, and total amount attributed to sales tax. However, those are not the only "detailed cost fields," as the PDE records contain approximately 74 different data fields. Tab 105, SA475-80.

75. ACLR reviewed reconciled PDE records for PY 2012-2013 and identified all PDE records containing sales tax amounts greater than $0.00. App. at Ex. 20, Mucke Aff. at ¶ 40; App. at Ex. 61, ACLR sales tax NAIRP.

RESPONSE: Admitted.

76. ACLR then identified the addresses for all pharmacies and reviewed applicable state and local tax laws to identify pertinent sales tax laws and their application to the sales tax PDEs ACLR had identified. App. at Ex. 20, Mucke Aff. at ¶ 41; App. at Ex. 61, ACLR sales tax NAIRP.

RESPONSE: Admitted.

77. During this review, ACLR identified sales taxes that were billed on PDEs from five states that did not impose sales taxes, sales taxes that were billed in the states of Louisiana and Minnesota that exempted PDEs where such taxes were statutorily exempt, and sales tax charges billed at impermissible tax rates exceeding 50% of PDE drug costs. App. at Ex. 20, Mucke Aff. at ¶ 42; App. at Ex. 61, ACLR sales tax NAIRP.

RESPONSE: Denied. Defendant agrees that ACLR identified PDE records containing data within the sales tax field in Louisiana; in Minnesota; in five states that ACLR concluded did not impose sales taxes; and in various states in which the amounts recorded in the sales tax field were greater than 50% of the drug costs recorded in the same PDEs. However, as demonstrated through the separate analysis performed for CMS by Health Integrity, the fact that amounts were recorded in the sales tax field does not necessarily mean that plan sponsors were charging CMS

for state sales tax. Rather, the amounts in those fields might reflect other forms of state taxes or fees that might be permissible under state law. Thus, ACLR's assertion that it identified "sales taxes that were billed" is inaccurate. Tab 122, SA655; Tab 124, SA671-72; Tab 139, SA743.

78. On August 21, 2015, ACLR submitted its sales tax NAIRP for PY 2012 and 2013 to CMS. App. at Ex. 61, ACLR sales tax NAIRP.

RESPONSE: Admitted.

79. Once a NAIRP is received by CMS, CMS should collaborate with ACLR to determine whether to refine or revise the NAIRP. App. at Ex. 2, C. Brown Dep. at 67:12-16.

RESPONSE: Defendant objects on the ground that this paragraph is a conclusion of law, not a statement of proposed fact. To the extent a response is required, qualified. Defendant agrees that Appendix E to the SOW discusses a collaborative process between CMS and the Part D RAC that applies to new audit issues that CMS is considering for approval. However, CMS's witness testified that the walk-through stages did not apply to ACLR's sales tax NAIRP because those steps occur "in the middle of a process where CMS is considering to approve" and this audit issue "never made it to this stage of a NAIRP approval process." Tab 21, A423; Tab 49, A604 at 43:14-22.

CMS denies ACLR's sales tax NAIRP

80. On September 3, 2015, CMS denied ACLR's sales tax NAIRP without scheduling a walk-through meeting as required by OY2 SOW Appendix E or collaborating with ACLR to determine whether to refine or revise the NAIRP as required by OY2 SOW Section 2.1.1. App. at Ex. 62, CMS denial of sales tax NAIRP; App. at Ex. 2, C. Brown Dep. at 67:12-16.

RESPONSE: Defendant objects on the ground that this paragraph is a conclusion of law, not a statement of proposed fact. To the extent a response is required, denied. Defendant agrees that it notified ACLR that ACLR's sales tax NAIRP was denied by email dated September 3, 2015. However, the walk-through process described in Appendix E of the SOW did not apply to

ACLR's sales tax NAIRP because that step occurs "in the middle of a process where CMS is considering to approve" and this audit issue "never made it to this stage of a NAIRP approval process." Tab 21, A423; Tab 49, A604 at 43:14-22.

81. No walk through was scheduled and ACLR was not given the opportunity to work with CMS/CPI to refine and approve or deny the sales tax NAIRP because CMS simply denied the NAIRP. App. at Ex. 6, CMS 30(b)(6) II at 49:3-6; App. at Ex. 49, S. Brown Dep at 42:6-43:22.

RESPONSE: Admitted.

82. The approval process in Appendix E of the OY2 SOW was not utilized for ACLR's sales tax NAIRP. App. at Ex. 49, S. Brown Dep. at 43:19-22.

RESPONSE: Denied. The timeline contained in Appendix E of the SOW reflects that the NAIRP process begins with the submission of a new proposal by ACLR, and concludes when "CMS provides complete approval, conditional approval, or denial of the NAIRP." In between, there are additional steps that can occur, including ACLR "conduct[ing] a walk-thru of the new issue at the next scheduled CMS/RAC Operations Meeting." No walk-through occurred for the sales tax NAIRP, because CMS already determined to deny the NAIRP based on the prior work performed by Health Integrity and the difficulties Health Integrity had uncovered in analyzing what was reported in the PDE sales tax field and whether those amounts were legitimate, which would require a state-by-state and prescription-by-prescription analysis. As CMS explained, no additional feedback or walk-through was provided because those steps occur "in the middle of a process where CMS is considering to approve" and this audit issue "never made it to this stage of a NAIRP approval process." Tab 21, A423; Tab 49, A604 at 43:14-22.

83. CMS's denial was solely predicated on its position that "this audit issue is currently open and active with another CMS contractor" and cited OY2 SOW Section 1.2.3 stating that "CMS/CPI consistently ensures RAC efforts are not duplicative and do not focus on improper payments that are already identified, being audited, and have been corrected/reimbursed elsewhere in CMS for the same audit issue." App. at Ex. 63, Excerpts of CMS 30(b)(6) Deposition in ACLR

II ("CMS 30(b)(6) II Dep.") at 55:1-22; 56:9-57:4; 196:9-21; App. at Ex. 49, S. Brown Dep at 42:9-12; App. at Ex. 62, CMS denial of sales tax NAIRP.

RESPONSE: Qualified. Defendant agrees that the only reason stated in CMS's email that notified ACLR of the denial of the sales tax NAIRP was that "this audit issue is currently open and active with another CMS contractor," with reference to SOW section 1.2.3 governing duplication of efforts by the Part D RAC. CMS also invited ACLR to contact CMS to further discuss the issue, but ACLR declined to do so. At the time of the sales tax NAIRP denial, CMS also was aware of the numerous logistical issues raised by Health Integrity with respect to pursuit of a recovery audit of potential improper sales tax charges based solely on the data contained in the PDE sales tax fields. Tab 62, A672; Tab 91, SA341 at 191:10-15; Tab 122, SA655; Tab 124, SA671-72; Tab 139, SA743.

84. On January 15, 2016, in its denial of ACLR's claim filed September 10, 2015, CMS informed ACLR that "the NBI MEDIC had commenced fraud and abuse work with respect to the Sales Tax Error Audit in October 30, 2014. Thus, in accordance with Section 1.2.3 of the SOW, ACLR could not also perform what would be duplicative audits on this same topic." App. at Ex. 64, CMS claim denial.

RESPONSE: Admitted.

85. ACLR identifies improper payments while the NBI MEDIC combats waste fraud and abuse and their processes would be entirely different. App. at Ex. 2, C. Brown Dep at 70:2-18; 92:13-16; App. at Ex. 9, Hoey Dep. at 58:16-59:2.

RESPONSE: Defendant objects on the ground that this paragraph is a conclusion of law, not a statement of proposed fact. To the extent a response is required, qualified. The cited deposition testimony does not support the assertion that the processes used by ACLR and Health Integrity "would be entirely different." The cited testimony is that "the MEDIC's process *could* be entirely different from the RAC's," not that the processes *would* be entirely different. Defendant agrees that Health Integrity, as the NBI MEDIC, was tasked with analyzing Part D

data, including PDE records, to identify fraud, waste, and abuse. ACLR, as the Part D RAC, was tasked with identifying improper payments for recoupment by CMS. While it was not Health Integrity's contractual purpose to identify improper payments for recoupment by CMS, if Health Integrity identified improper payments, the result of that analysis could be the deletion of improper PDE records, having the same offsetting effect on plan sponsor payments as a recoupment accomplished through an approved audit issue completed by ACLR. Moreover, in the context of ACLR's proposed sales tax NAIRP, Health Integrity already had examined the same exact PDE records for the same years for the same issue, and had identified logistical problems with assuming that any amount recorded in the sales tax fields on those PDEs actually was an improper sales tax charge. ACLR's NAIRP did not address those issues at all. Tab 2, A26 at 92:4-16; Ex 61, A663; Tab 122, SA655; Tab 124, SA671-72; Tab 139, SA743.

86. The NBI MEDIC does not recover improper payments that are identified. App. at Ex. 63, CMS 30(b)(6) II Dep. at 95:2-7.

RESPONSE: Denied. The reference for this proposed uncontroverted fact, page 95 of a Rule 30(b)(6) deposition, was omitted from ACLR's appendix. Moreover, if Health Integrity identified improper payments in the course of its work as the NBI MEDIC, the result of that analysis could be the deletion of improper PDE records by plan sponsors, which would have the same offsetting effect on plan sponsor payments as a recoupment accomplished through an approved audit issue completed by ACLR. Tab 2, A26 at 92:4-16.

87. When ACLR submitted its sales tax NAIRP, the NBI MEDIC wasn't doing any more sales tax reviews. App. at Ex. 66, Excerpts of deposition of Rosalind Abankwah ("Abankwah Dep.") at 57:16-58:1.

RESPONSE: Qualified. [redacted]

[redacted]s and kept

[redacted]

[redacted]. Tab 93, SA366-68 at 126:5-128:15; Tab 97, SA392-94 at 91:3-93:15, SA395-96 at 133:14-134:2, SA397-98 at 141:22-142:7; Tab 98, SA410-11 at 50:22-51:16; Tab 126, SA688.

88. After August 10, 2015, the NBI MEDIC did not conduct any further analysis of any of the Minnesota PDE records identified in ACLR's sales tax NAIRP. App. at Ex. 63, CMS 30(b)(6) II Dep. at 179:22-180:5; See App. at Ex. 65, Excerpts of deposition of Matthew Farabaugh as corporate representative for Health Integrity, LLC ("NBI MEDIC 30(b)(6) Dep.") at 127:1-5; App. at Ex. 66, Abankwah Dep. at 58:7-10.

RESPONSE: Qualified. [redacted]

[redacted]. Tab 93, SA366-68 at 126:5-128:15; Tab 97, SA392-94 at 91:3-93:15, SA395-96 at 133:14-134:2, SA397-98 at 141:22-142:7; Tab 98, SA410-11 at 50:22-51:16; Tab 126, SA688.

89. After July 2015, the NBI MEDIC did no further work on PDE records and improper sales taxes with respect to the states of Delaware, Alaska, Alabama, New Hampshire, Montana, and Oregon. App. at Ex. 65, NBI MEDIC 30(b)(6) Dep. at 249:6-22.

RESPONSE: Qualified. [redacted]

[redacted]. Tab 93, SA366-68 at 126:5-128:15; Tab 97, SA392-94 at 91:3-93:15, SA395-96 at 133:14-134:2, SA397-98 at 141:22-142:7; Tab 98, SA410-11 at 50:22-51:16; Tab 126, SA688.

90. In its sales tax NAIRP, ACLR identified improper payments related to sales tax included in PDE records in amounts totaling $5,518,803 in states that did not impose a sales tax; $1,623,530 for excessive tax rates; and $32,028,178 and $619,184, 285 in the states of Louisiana and Minnesota respectively, which exempt such transactions. App. at Ex. 61, ACLR sales tax NAIRP.

RESPONSE: Denied. Defendant agrees that ACLR's sales tax NAIRP identified total PDE payments (meaning the total amount paid on PDEs, *not* the amount reported in the sales tax field on those PDEs) of $5,518,803 in states that ACLR concluded did not impose a sales tax; $1,623,530 in various states in which the amount recorded in the sales tax field was greater than 50% of the drug ingredient costs; $32,028,178 in Louisiana; and $619,184,285 in Minnesota. Notably, those amounts reflected the total amount billed on prescriptions in which any amount was recorded in the sales tax field, not the amount of alleged sales tax itself. And based on Health Integrity's analysis, it appeared that the vast majority of the amounts recorded in the sales tax field on those PDEs actually related to charges other than state sales tax. Tab 61, A670; Tab 91, SA332-33 at 147:15-148:7; Tab 122, SA655; Tab 124, SA671-72; Tab 139, SA743.

91. ACLR's contingency fee was $75,459,194 based upon improper payments of $626,326,618 on the plan year 2012 and 2013 sales tax NAIRP for Minnesota, the five states that do not charge sales taxes, and sales tax charges billed at impermissible tax rates exceeding 50% of PDE drug costs. App. at Ex. 20, Mucke Aff. at ¶ 45.

RESPONSE: Denied. Defendant agrees as to the mathematical calculation performed by ACLR, that 15% of $10 million and 12% of the remaining $616,326,618 amounts to $75,459,194. However, the parties' contract only allows for payment of contingency fees to

ACLR based off of overpayments actually recouped by CMS, not based on potential overpayments identified by ACLR but not recouped. Tab 21, A392; Tab 91, SA299 at 39:18-22, SA302 at 59:11-22.

[ACLR Alleges that] CMS Fails to Seek
the Recovery of Billions of Dollars of Improper Payments

92. In November 2010, Department of Health and Human Services ("HHS") released the Fiscal Year 2010 Agency Financial Report which identified invalid and/or inaccurate PDE records under the Part D program at an estimated error rate of 12.7 percent for payments from January 1, 2007 through December 31, 2007 and estimated a gross amount of payment error totaling $5.4 billion. App. at Ex. 67, HHS 2010 Financial Report excerpts at section 10:10 (2).

RESPONSE: Qualified. Defendant agrees that the Department of Health and Human Services (HHS) stated in its FY 2010 Agency Financial Report that the Payment Error Related to Prescription Drug Event Data Validation (PEPV), which measures errors due to invalid and/or inaccurate PDE records that impact the Part D Low Income Cost Sharing Subsidy and reinsurance payments, reported an estimated error rate of 12.7% for 2007, and a gross payment error totaling $5.4 billion. That is a gross error rate, meaning that it includes both overpayments and underpayments, not a net error rate. In other words, if the testing process identified $1 billion of underpayments and $1 billion of overpayments, the reported result would be $2 billion in payment errors, even though the net effect of the underpayments and overpayments would be $0. Tab 67, A708-09.

93. The Medicare Part D payment errors for 2010 were estimated to be $5.3 billion. App. Ex. 68, Medicare Part C and D FY 2011 Payment Error Reporting, March 23, 2012, page 9.

RESPONSE: Qualified. Defendant agrees that HHS stated in a FY 2011 Payment Error Reporting presentation that the estimated PEPV error rate for fiscal year 2010 was 12.74%, with a gross payment error totaling $5.3 billion. That is a gross error rate, meaning that it includes

both overpayments and underpayments, not a net error rate. In other words, if the testing process identified $1 billion of underpayments and $1 billion of overpayments, the reported result would be $2 billion in payment errors, even though the net effect of the underpayments and overpayments would be $0. Tab 68, A719.

94. The Medicare Part D error rate for 2012 was $1.6 billion and the estimated loss was $1.1 billion. App. at Ex. 69, HHS FY 2012 Agency Financial Report excerpts at page 173; App. at Ex. 6, CMS 30(b)(6) Dep. at 151:1-7; 157:13-16.

RESPONSE: Qualified. Defendant agrees that HHS stated in its FY 2012 Agency Financial Report that the estimated Medicare Part D error rate for fiscal year 2012 was 3.1%, with a gross payment error totaling $1.6 billion, with estimated net losses of $1.1 billion. That error rate was not limited to the estimated PEPV error rate. Tab 69, A723.

95. The Medicare Part D payment error estimate for fiscal year 2013 was $2.1 billion. App. Ex. 70, September 29, 2014 email at page 335.

RESPONSE: Qualified. Defendant agrees that HHS reported an estimated Medicare Part D gross error of $2.1 billion in fiscal year 2013, based on calendar year 2011 data. That error rate was not limited to the estimated PEPV error rate. That is a gross error rate, meaning that it includes both overpayments and underpayments, not a net error rate. In other words, if the testing process identified $1 billion of underpayments and $1 billion of overpayments, the reported result would be $2 billion in payment errors, even though the net effect of the underpayments and overpayments would be $0. Tab 70, A731.

96. In 2014, the federal government spent $58 billion on Medicare Part D and an estimated $1.9 billion of this was improper payments due to errors such as the submission of duplicate claims for the same service. App. at Ex. 15, GAO Report at page 2; See App. at Ex. 6, CMS 30(b)(6) Dep. at 145:15-146:15; 147:17-148:11.

RESPONSE: Qualified. Defendant agrees that GAO reported that in 2014, CMS spent $58 billion on the Medicare Part D program, and that an estimated $1.9 billion of that amount

was for improper payments. However, the $1.9 billion figure included both underpayments and overpayments, not a net figure reflecting only amounts overpaid by CMS. Tab 15, A297.

97. During the course of the Part D RAC Contract, ACLR identified and submitted to CMS Part D improper payments totaling $3 billion. App. at Ex. 71, November 13, 2013 email; App. at Ex. 20, Mucke Aff. at ¶ 46.

RESPONSE: Denied. Defendant agrees that, as of November 2013, ACLR reported to CMS that ACLR had identified $1.05 billion of alleged improper payments, and that ACLR now contends that, through the end of the Part D RAC contract, ACLR had identified a total of $3 billion in alleged improper payments. However, ACLR agrees that the amounts it identifies at the outset of any audit issue, such as in a NAIRP, are only "estimates" of possible improper payments. Thus, it is not accurate to state that ACLR identified $3 billion of actual improper payments, because those amounts were never validated or confirmed through requests for information from plan sponsors. Tab 71, A741; Tab 91, SA345 at 210:5-21.

98. As of August 2015, CMS had approved 1 of the 15 audit proposals from ACLR since the beginning of the Part D RAC. App. at Ex. 15, GAO Report at page 2.

RESPONSE: Denied. At the time the GAO prepared its report, and based on the way it characterized the audit issues by combining similar issues together, the GAO reported that ACLR had completed only 1 audit issue. However, ACLR submitted audit proposals or NAIRPs for seven audit issues that CMS allowed ACLR to pursue: (1) payments made for excluded providers in 2007; (2) payments made for excluded providers in 2008-2011; (3) payments made for excluded providers in 2012-2013; (4) payments involving unauthorized prescribers in 2009-2012; (5) payments made for unauthorized prescribers in 2013; (6) payments involving DEA schedule drugs in 2010-2011; and (7) payments involving DEA schedule drugs in 2012-2013. Tab 140, SA746-47.

99. As of May 2015, CMS had collected less than $10 million in Part D improper payments. *Id.* at page 2.

RESPONSE: Admitted.

100. Through the date of this filing, CMS Part D improper payment collections, upon which ACLR was paid, totaled $11.9 million. App. at Ex. 20, Mucke Aff. at ¶ 47.

RESPONSE: Denied. As of March 2017, CMS reported that it had recouped approximately $13.9 million in Part D improper payments resulting from ACLR's approved audit issues, with several million dollars of additional improper payments identified but subject to pending appeals. Tab 140, SA747.

DEFENDANT'S ADDITIONAL PROPOSED FINDINGS OF UNCONTROVERTED FACT

Medicare Part D Background

101. Coverage for the Medicare Part D drug benefit is provided by plan sponsors, which are private prescription drug plans. Tab 4, A30.

102. The Medicare Part D program operates on a cost-sharing basis. Plan sponsors pay prescription drug costs on behalf of their beneficiaries, and are compensated for those costs by both the beneficiaries and the Government. Tab 7, A186 at § 1.1.

103. All Part D plans are required to provide a minimum set of prescription drug benefits, typically referred to as the "basic" benefit. For additional premiums, plans can offer benefits that exceed the basic benefits, but the Government only pays for the basic benefit. Tab 105, SA474 at § 1-2.

104. Plan sponsors are paid for Part D basic benefits through four mechanisms: a direct subsidy; a low income subsidy; a reinsurance subsidy; and risk sharing or risk corridor payments. *Id.*

105. CMS pays plan sponsors a monthly prospective payment throughout each year for each beneficiary enrolled in the plan. Tab 141, SA750.

106. After the end of each year, CMS reconciles the prospective amounts paid to a plan sponsor with the plan's actual levels of enrollment, risk factors, levels of incurred allowable drug costs, reinsurance amounts, and low-income subsidies. *Id.*; Tab 7 A186 at § 1.1.

107. The payment reconciliation process results in CMS either paying additional funds to a plan sponsor (if the plan's actual costs were greater than the prospective payments made throughout the year), or recouping funds from a plan sponsor (if the plan's actual costs were less than the prospective payments made throughout the year). Tab 142, SA753.

108. When a Medicare Part D beneficiary fills a prescription, the plan sponsor submits an electronic prescription drug event (PDE) record to CMS. PDE records contain information concerning the type of drug prescribed, the drug cost, payment details, and other information to allow CMS to administer the Part D benefit program. Tab 15, A303.

109. PDE records contain approximately 74 data fields (the number has changed over time), although not every field is used in every prescription. Tab 105, SA475-80; Tab 92, SA363 at 129:10-14.

The Part D RAC Contracting Process

110. CMS issued a sources sought notice on October 18, 2010, using the General Services Administration's Federal Supply Schedule, "to determine the availability of small businesses that have the capability to support CMS in identifying and recouping underpayments and overpayments made under the Medicare Prescription Drug Coverage Program, also known as Medicare Part D." Tab 76, SA002.

111. At the time ACLR responded to CMS's sources sought notice, ACLR itself had no prior experience analyzing the substance of Part D claims to determine whether they were proper or improper claims, no prior experience conducting recovery audits related to any Medicare program, and had never before entered into any Government contract. Tab 91, SA308 at 82:11-16, SA309-11 at 83:17-85:6; Tab 94, SA372-73 at 108:16-109:2.

112. On December 2, 2010, CMS issued a request for quotations (RFQ), stating that CMS "intends to award a Firm-Fixed Price Contingency Fee Task Order for the subject work" under the Part D RAC program. Tab 77, SA005.

113. The RFQ contained a statement of objectives (SOO) prepared by CMS. According to the SOO, the mission of the Part D RAC would be to "reduce Medicare improper payments through the efficient detection and collection of overpayments, the identification of underpayments, and the implementation of actions that will prevent future improper payments." Tab 4, A31.

114. The SOO set forth a series of objectives for the Part D RAC, and stated that the Part D RAC "shall furnish all the necessary services . . . not otherwise provided by the Government, as needed to meet the objectives." *Id.*

115. Among other things, the SOO tasked the Part D RAC with "[e]stablish[ing] a schedule of deliverables necessary to meet the objectives listed above as well as program initiatives." Tab 4, A33.

116. To satisfy Government information technology security requirements, the SOO also provided that the Part D RAC would be required to obtain "a formal Government Authorization to Operate (ATO)." Tab 4, A35.

117. ACLR submitted a technical package to CMS in response to the RFQ. Tab 5, A42.

118. ACLR's response to the RFQ included a proposed performance work statement (PWS) that was drafted entirely by ACLR. *Id.* at A46; Tab 90, SA230 at 23:2-5.

The Part D RAC Contract

119. CMS issued task order HHSM-500-2011-00006G for "Recovery Audit Services in Support of Medicare Part D" under ACLR's General Services Administration contract number GS-23F-0074W on January 13, 2011. Tab 7, A157.

120. The task order incorporated ACLR's proposed PWS, and stated that ACLR "shall furnish all necessary services . . . not otherwise provided by the Government, as needed to perform the requirements set forth in" the PWS. *Id.* at A159.

121. The task order specified:

> All payments shall be paid only on a contingency basis. The recovery audit contractor will receive 7.5% of all amounts collected. The contingency fees shall be paid once the recovery audit contractor collects the Medicare overpayments. The recovery audit contractor shall be paid a percentage of the amount that is collected through their recovery efforts. The recovery audit contractor shall not receive any payments for the identification of the underpayments or overpayments not recovered/collected.

Id.

122. The task order also specified that ACLR's performance under the contract was subject to any applicable statutes and regulations, and that new legislation or regulations might be enacted that could impact ACLR's performance under the contract.

> In addition to the performance requirement of this contract as set forth under Performance Work Statement, the Contractor may be required to comply with the requirements of any revisions in legislation or regulations which may be enacted or implemented

> during the period of performance of this contract, and are directly applicable to the performance requirements of this contract.

Id. at A170.

123. Under the Part D RAC contract, ACLR was tasked with reviewing reconciled PDE records, *i.e.*, PDE records that already had been adjusted through the year-end reconciliation process. Tab 21, A400 at § 1.2.3; Tab 90, SA242 at 116:2-4.

124. Under the Part D RAC process, after ACLR identified any improper payments, and following the completion of any appeals by the plan sponsors, CMS would recoup the finalized overpayment amounts by offsetting those amounts from plan sponsors' ongoing monthly prospective Part D payments. Once the offset occurred, CMS would be deemed to have recouped the overpayments, and ACLR would be paid its contingent fee under the RAC contract calculated off of the recouped amounts. Tab 97, SA387-89 at 22:14-24:11, SA402-03 at 269:5-270:10.

125. ACLR's position is that, under the PWS, ACLR had authority to conduct any audits it wished to pursue – including any audit for duplicate payments; to determine which Part D payments were improper based solely on ACLR's review of the PDE data without any oversight or validation by CMS; and to send notices to plan sponsors identifying any PDEs determined by ACLR to be improper payments without prior review or approval by CMS. Tab 90, SA239 at 105:1-7, SA245 at 119:7-13, SA247 at 122:15-21.

126. The PWS stated in the description of ACLR's proposed work plan for analyzing duplicate payments stated that ACLR "anticipate[d] CMS revisions to our process." Tab 7, A191.

127. The PWS stated that, for those plan sponsors identified by ACLR as having the most significant errors through a review of PDE data, ACLR would "recommend them, and solicit CMS' approval for, conducting documentation audits." *Id.* at A193.

128. The PWS stated that ACLR "anticipate[d] that some of our recommendations . . . will require numerous discussions and considerable analysis by ACLR, CMS, Plan Sponsors, as well as other stakeholders." *Id.* at A188.

129. The PWS stated, in connection with ACLR's proposed process for conducting statistical sampling, that ACLR "anticipate[d] that CMS will want to discuss and approve this methodology." *Id.* at A194.

130. The PWS stated that "[u]pon contract award [ACLR] will standardize all CMS approved activities and the administration of [ACLR's] processes in accordance with CMS guidance and policies and modify them as requested." *Id.* at A197.

131. The PWS included a schedule of deliverables. The PWS stated that "this Schedule of Deliverables will be modified as work progresses and upon feedback received from CMS and subsequent modification and approval." *Id.* at A212.

Modifications to the Part D RAC Contract

132. ACLR's Part D RAC task order was modified 16 times. Among other things, those modifications extended the base year of performance through December 31, 2013 (approximately two years from contract award) and allowed for two 12-month option periods that were exercised, continuing the period of contract performance through December 31, 2015. Tab 80, SA117; Tab 21, A388; Tab 22, A430.

133. An additional administrative and appeals option period continued through December 31, 2017, for processing any appeals by plan sponsors challenging improper payment findings under any approved ACLR recovery audits. Tab 81, SA118; Tab 82, SA119.

134. On several occasions, CMS issued modifications that increased ACLR's contingent fee from the 7.5% provided in the initial task order. In modification 3 dated January 31, 2012, CMS provided for an increase in ACLR's contingent fee to 12% for a recovery audit being conducted by ACLR that focused on identifying 2007 PDEs that involved providers who were excluded from participation in Federal health care programs. Tab 28, A513.

135. Modification 11, dated November 19, 2013, increased ACLR's contingent fee to 16% for ACLR's recovery audit that focused on 2008 through 2011 PDEs involving excluded providers. Tab 79, SA116.

136. ACLR understood, at the time those modifications were issued, that CMS intended the increased contingent fees as a means of compensating ACLR for any delays or difficulties ACLR had experienced in working with CMS to get the Part D RAC program up and running over the first few years of the RAC contract, before any significant contingent fees had begun to flow to ACLR as a result of recovery audit activities. Tab 90, SA236 at 89:8-14.

137. During the first year of the contract, ACLR learned from CMS that CMS intended to develop a statement of work (SOW) to replace ACLR's PWS that was attached to the initial task order. *Id.* at SA231-34 at 25:18-28:14.

138. CMS provided a draft of the SOW to ACLR on December 9, 2011. The parties continued to negotiate and revise the draft SOW until it was finalized and issued along with contract modification 13 on December 31, 2013. Tab 21, A388; Tab 26, A488.

139. The SOW replaced the PWS in its entirety, such that the PWS was no longer in effect. Tab 90, SA237 at 90:12-20.

140. Although the PWS remained a part of the parties' contract until it was replaced with the SOW in modification 13 at the end of 2013, ACLR agreed during the first year of performance in December 2011 that ACLR would "continue executing only those portions of the contract that are consistent with current CMS expectations (e.g. not issuing demand letters) until such time as the PWS/SOW issues have been resolved." Tab 110, SA602.

141. ACLR understood that it would not be performing under the terms of the PWS while the SOW was being drafted and finalized. Tab 90, SA248-49 at 124:18-125:9.

142. ACLR agreed not to send improper payment notices to any plan sponsors related to the alleged 2007 duplicate payments that ACLR had referenced during a November 30, 2011, conference call. *Id.* at SA250 at 131:8-11.

143. Until the SOW was finalized, the only recovery audits ACLR pursued were ones authorized by CMS through formal contract modifications: 2007 PDEs involving potential excluded providers (modification 3); 2008-2011 PDEs involving potential unauthorized prescribers (modifications 6, 11); and 2009 PDEs involving potential duplicate payments submitted by three specific plans (modification 8). Tab 28; Tab 36; Tab 78; Tab 79.

144. Modification 13 that accompanied the SOW continued the prior task order provision that

> All payments shall be paid only on a contingency basis. The recovery audit contractor will receive the percentage specified below of all amounts collected. The contingency fees shall be paid once CMS collects the Medicare overpayments. The recovery audit contractor shall be paid a percentage of the amount that is collected through their recovery efforts . . . . The recovery audit contractor shall not receive any payments for the identification of the underpayments or overpayments not recovered/collected.

Tab 21, A392.

145. Modification 13 adjusted ACLR's contingent fee rate again, increasing the rate for the 2008 through 2011 excluded provider audit issue to 28%. The parties also agreed to a new contingency fee rate for all new approved audit issues, setting the rate at 15% for the first $10 million in recoveries and then 12% for any recoveries above $10 million per approved issue. *Id.*

146. The SOW provided that

> CMS/CPI determines the specific criteria on which the Part D RAC must submit to CMS as improper payments and new audit issues. To direct the Part D RAC's review, CMS/CPI mandates submission of potential improper payments by contract, issue type, and audit year. CMS further defines the audit scope to include the exact audit issue to be reviewed.
> . . .
> As the Part D RAC progresses, new audit issues may be approved and added to the RAC's audit scope. In addition to the audit issues already approved by CMS/CPI, audit issues may be expanded to include new issues during the RAC process. A new audit issue must first be proposed to CMS for approval.

Tab 21, A399 at § 1.2.1.

147. The SOW set forth a process by which ACLR was required to submit a new audit issue review package (NAIRP) for each audit issue it proposed to pursue. ACLR was required to include in its NAIRPs "the issue type, audit scope, recovery estimate, a sample of PDE records, applicable law, policies, etc. and recommendation for automated or complex review." *Id.*

148. An automated review was described as a recovery audit completed entirely through a review of the data contained in the PDE records. *Id.*

149. A complex review was defined as a recovery audit that would require ACLR to request and review additional information from plan sponsors (such as copies of prescriptions or

other documentation) to compare to the data contained in the PDE records, to determine the accuracy of the PDE data submissions. *Id.*

150. The SOW stated that ACLR "must receive approval from CMS/CPI prior to commencing recovery audit activities." Tab 21, A402 at § 2.1.1.

151. Following the submission of a NAIRP for a proposed new audit issue, the SOW provided that ACLR would "work[] with CMS/CPI to refine and approve or deny the NAIRP. Once approved the RAC begins recovery audit activities." *Id.*

152. Under the SOW, CMS had to approve any audit issue for ACLR to be permitted to commence and complete that recovery audit. Tab 91, SA303-04 at 63:20-64:11.

153. The SOW NAIRP process specified that, if CMS elected to deny any NAIRP, "CMS shall provide [ACLR] with a written explanation as to the reasons for the denial." Tab 21, A423-24 at App. E.

154. Under the SOW, ACLR did not have the right to proceed with an audit, absent approval from CMS. Tab 91, SA303-04 at 63:20-64:11.

155. ACLR stated that CMS had the right under the contract to determine what the methodology would be for any approved audit issue that ACLR pursued, or to "dictate" the methodology it wanted ACLR to use. Tab 90, SA262-64 at 189:20-191:10.

156. The SOW stated that after that recoupment and appeals process was completed, ACLR "will receive a contingency payment once the full overpayment amount has been recouped from the plan sponsor." Tab 21, A405 at § 3.2.2.

157. The parties agreed to a revised SOW that was issued as part of contract modification 16 and went into effect as of January 1, 2015. Tab 22, A430.

158. The only substantive amendment to the SOW was to change the two-level appeals process to a three-level appeals process, with the final level of appeals resolved by the CMS Administrator's designee. Tab 22, A447 at App. A, A454 at App. C.

159. The three-level appeals process contained in the revised SOW was consistent with provisions of a final rule, known as CMS-4159-F, issued by CMS on May 23, 2014, following notice and comment. *See* 79 Fed. Reg. 29844 (May 23, 2014).

160. The addition of the optional third-level appeal for the Part D RAC program was intended to replicate the appeals process in place for the RAC programs under Parts A and B. Tab 99, SA417-19 at 63:21-65:1.

Other Part D Contractors Performing Services For CMS: The Data Validation Contractor

161. CMS contracted with Livanta LLC (Livanta) on September 30, 2011, to serve as the data validator for the Part D RAC. Tab 102, SA428.

162. Livanta's contract required it to "measure the accuracy rate of the Part D RAC," by reviewing "improper payments identified by [ACLR] to determine if they are accurate." *Id.* at SA442.

163. Livanta also was contracted to "review and approve/disapprove improper payment referrals [and] receive and review New Audit Issues [ACLR] wants to pursue for improper payments." *Id.*

164. Livanta's contract provided that "CMS will determine whether [ACLR's] accuracy shall be determined by sampling or as a 100% review." *Id.* at SA445.

165. CMS tasked Livanta with reviewing 100% of ACLR's proposed improper payments per audit issue. Tab 92, SA358-59 at 15:19-16:3, SA360 at 28:13-19, SA361 at 35:16-18, SA362 at 37:5-12.

166. ACLR learned of Livanta's role as the data validation contractor during the first year of ACLR's contract, prior to CMS authorizing ACLR to proceed with any specific audit issues. For instance, in modification 3, issued January 31, 2012, CMS and ACLR agreed to a timetable for ACLR to complete its audit of 2007 PDE records for excluded providers that included deadlines for Livanta to complete its validation review. Tab 28, A515.

167. Modification 4 issued on April 5, 2012, included a process by which ACLR and Livanta were to resolve any disputes concerning Livanta's validation of ACLR's audits. Under those procedures, ACLR was required to "either accept or reject [Livanta's] validation findings." The modification provided that if ACLR and Livanta "cannot come to a resolution, CMS shall make the final decision, which cannot be reviewed or contested by either" ACLR or Livanta. Tab 33, A542-43.

168. ACLR was not authorized to send notification of improper payment letters to plan sponsors prior to the validation of ACLR's findings by Livanta. Tab 54, A627.

169. The SOW stated, "CMS does not need any statutory or regulatory reference to deny a RAC finding." And "CMS also has the right to establish minimums and thresholds that the Part D RAC findings must meet to be considered for recoupment." Tab 21, A403 at § 2.2.1.

Other Part D Contractors Performing Services For CMS: The NBI MEDIC

170. CMS contracted with Health Integrity, LLC (Health Integrity) to serve as the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC). Health Integrity's role as the NBI MEDIC is to assist CMS in the "[redacted]." Tab 93, SA365 at 10:6-11.

171. Health Integrity was tasked with examining the Part D program to look for fraud, waste, and abuse, that could include, among other things, "[a]llegations that prescription drugs or

other items or services were not received"; allegations that a provider or plan sponsor "received a Medicare benefit of monetary value . . . to which he or she is not entitled under current Medicare law, regulations, or policy"; "[m]isrepresenting the . . . prescription drug event data to increase payments"; and "[b]illing Medicare for costs not incurred or which were attributable to non-Medicare activities." Tab 104, SA468-70.

172. Health Integrity, as the NBI MEDIC, was tasked with "recommend[ing] recovery of overpayments whenever it is determined that Medicare has erroneously paid." *Id.* at SA471.

173. Health Integrity's contract provided that it "may furnish requested specific information on ongoing fraud investigations and on individually identifiable protected health information to any Medicare contractor." *Id.* at SA472.

174. ACLR's SOW states that ACLR "shall cooperate and coordinate with stakeholders other than CMS, including Affiliated Contractors (ACs), and other entities as appropriate." Tab 22, A445 at § 6.2.

ACLR's Completed Audit Issues

175. CMS authorized ACLR to pursue the following audits: (1) payments made for excluded providers in 2007; (2) payments made for excluded providers in 2008-2011; (3) payments made for excluded providers in 2012-2013; (4) payments involving unauthorized prescribers in 2009-2012; (5) payments made for unauthorized prescribers in 2013; (6) payments involving DEA schedule drugs in 2010-2011; and (7) payments involving DEA schedule drugs in 2012-2013. Tab 140, SA746-47.

176. ACLR was paid its contingent fees on the completed recovery audits for which there either were no appeals or for which the appeals have been finalized. Tab 91, SA306-07 at 80:12-81:4.

ACLR's Proposed Audit Issues: 2007 Duplicate Payments

177. One of the audit issues that ACLR contemplated pursuing when it prepared the PWS was potential duplicate payments, *i.e.*, duplicate payments by CMS for the same exact prescription. Tab 7, A190, A198.

178. CMS asked ACLR to submit a draft of a proposed process for "how ACLR would go about auditing a plan on . . . duplicate payments" on August 25 and September 26, 2011. Tab 108, SA498; Tab 109, SA601.

179. ACLR sent CMS an email on September 30, 2011, in which ACLR set forth the seven specific fields within the PDE records that ACLR proposed to use to identify potential duplicate payments. Tab 109, SA600.

180. That was the first time ACLR informed CMS of the specific process ACLR proposed to use for identifying potential duplicate payments within the PDE record data. As ACLR noted in its email, "if there are multiple PDE records containing the same criteria for all seven data fields then there is the *possibility* that there is a duplicate payment." Tab 90, SA240-41 at 111:3-112:9; Tab 109, SA600 (emphasis added).

181. CMS began transmitting Part D PDE records to ACLR on November 17, 2011. The transmittal began with 2007 PDE records, and once the 2007 PDE record transmissions were completed, ACLR began to receive PDE records for subsequent years from CMS over the next several weeks. Tab 83, SA121; Tab 90, SA243 at 117:16-22, SA255 at 151:14-19.

182. ACLR began reviewing the 2007 PDE records shortly after their receipt from CMS and in advance of a November 30, 2011 conference call between ACLR and CMS. Tab 90, SA243-44 at 117:12-118:20.

183. During that conference call, ACLR's founder, Christopher Mucke, informed CMS for the first time that ACLR already had identified approximately $175 million in potential duplicate payments in the 2007 PDE records, and that ACLR was prepared to begin sending notices of improper payments to all of the plan sponsors identifying those payments the following week. *Id.* at SA243-44 at 117:12-118:20, SA247 at 122:15-21.

184. ACLR had not yet identified for CMS the specific PDE records that ACLR contended were duplicate payments, nor had anyone else validated ACLR's findings. *Id.* at SA244-45 at 118:21-119:15.

185. CMS had not yet implemented the framework for offsetting any actual overpayments from plan sponsors' ongoing monthly Part D payments, and thus there was no reimbursement process in place. Tab 99, SA414-16 at 56:21-58:18.

186. CMS informed ACLR that CMS did not want ACLR to begin sending improper payment notices to plan sponsors related to the 2007 PDE records. Tab 100, SA423-24 at 87:7-88:11.

187. ACLR continued analyzing the 2007 PDE records for potential duplicate payments, and subsequently determined that it had identified a total of $313,808,241 potential duplicate payments for 2007. Tab 106, SA481.

188. ACLR discussed the potential 2007 duplicate payment audit issue one more time with CMS, in January 2012. Tab 90, SA253-54 at 149:12-150:13.

189. Other than sharing the $313 million total figure with CMS, ACLR did not provide CMS with any documentation or identification of the specific plan sponsor contracts or PDE records that constituted that $313 million figure until early 2015, around the time ACLR submitted its certified claim that led to *ACLR I*. *Id.* at SA286-87 at 288:5-289:17.

190. ACLR did not provide CMS with copies of the specific 2007 PDEs that ACLR contended amounted to duplicate payments until either the submission of its certified claim in March 2015 at the earliest or, perhaps, not until discovery during the litigation in *ACLR I*, in 2016. *Id.* at SA256-57 at 154:22-155:9, SA287-88 at 289:17-290:13.

191. In *ACLR I*, ACLR seeks to recover $23,535,618, which it contends are the contingent fees it would have received if it had been permitted to proceed with the recovery audit for 2007 potential duplicate payments, and if CMS had, in fact, recovered the entirety of the $313,808,241 in potential duplicate payments that ACLR claims it identified within the 2007 PDE records. Tab 85, SA146-47; Tab 90, SA278 at 272:3-13.

192. That contingent fee is calculated by multiplying the 7.5% contingency fee rate that was contained in the Part D RAC contract in 2011 times the total $313.8 million figure. Tab 90, SA292 at 307:11-18.

193. ACLR has no knowledge that CMS actually recovered any, nor all, of the $313 million in potential duplicate payments found by ACLR. *Id.* at SA238 at 94:1-8, SA279 at 273:6-18.

194. ACLR has characterized the potential improper payments that it identified at the outset of any audit issue as only "estimates" of the actual improper payments that it expects to confirm through the recovery audit process. Tab 91, SA345 at 210:5-21.

ACLR's Proposed Audit Issues: 2010 Duplicate Payments

195. After the issuance of modification 13 and the incorporation of the SOW into the Part D RAC contract, ACLR again proposed a recovery audit for potential duplicate payments, this time using PDE records from 2010 through 2012. Following the submission of an initial

NAIRP in January 2014 and multiple revisions, ACLR submitted a final revised NAIRP submission for this audit issue on May 13, 2014. Tab 107, SA492.

196. ACLR's revised NAIRP provided additional information regarding how ACLR intended to identify potential duplicate payments using the data in the PDE records. Pursuant to CMS's request, ACLR agreed that the 2010-2012 duplicate payment audit issue would be conducted as a complex, rather than automated, review under the SOW. *Id.* at SA493.

197. Under the complex review procedures, ACLR would be required to request information from plan sponsors after ACLR compiled a preliminary list of potential duplicate payments from the PDE data, and then review documentation received from the sponsors to determine whether the PDE records were, in fact, duplicate payments based on the underlying documentation submitted by the plan sponsors. *Id.* at SA494; Tab 21, A399-400 at § 1.2.1.

198. According to ACLR's revised NAIRP, ACLR would first look for an "exact match" between multiple PDEs containing the exact same data contained in five different PDE fields. From those results, ACLR agreed to exclude from its findings any PDE records related to partial fills (partial prescriptions given to patients while pharmacies are awaiting the supply to fill the remainder of the prescription dosage, for instance); long term care; vaccination administrative fees; and prescriptions transitioning from retail to mail order pharmacies. Tab 107, SA493; Tab 90, SA258-59 at 185:22-186:11.

199. Once ACLR identified the exact matches using the specified PDE fields and eliminated the categories of prescriptions described above, ACLR agreed to examine the length of time that elapsed between each pair of potentially duplicative PDEs. Under that process, "the days elapsed between two PDE selected as a result of the exact match review is determined and compared to the days supply of the originating PDE." If the days elapsed was less than 50% of

the days' supply of medication contained in the original PDE, ACLR would identify the subsequent PDE record as "potentially duplicative." Following the completion of that process, ACLR would generate a list of potential duplicate payments for which requests for information would be sent to plan sponsors "requesting detailed prescription data for all potentially duplicative PDEs." Tab 90, SA259-61 at 186:12-188:1; Tab 107, SA493-94.

200. ACLR then would review the documentary submissions received from plan sponsors and generate an improper payment review package identifying those PDEs that ACLR continued to believe were duplicates, to be reviewed by the data validation contractor Livanta. *Id.*

201. CMS notified ACLR on May 28, 2014, that CMS had approved the revised duplicate payment NAIRP, but that CMS was continuing to review ACLR's proposed request for information prior to ACLR sending the notices to the plan sponsors. CMS asked ACLR to submit the PDE records associated with its potential duplicate payment findings to CMS for review prior to notifications being sent to the plan sponsors. Tab 112, SA606.

202. ACLR submitted all of the 2010 through 2012 PDE records identified as potentially duplicative to CMS on June 9, 2014, and ACLR informed CMS that it anticipated sending notification letters requesting information to all of the affected plan sponsors "no later than" two days later, June 11, 2014. Tab 48, A597-98.

203. CMS responded the next day, informing ACLR that CMS could not read any of the PDE files submitted by ACLR due to a formatting issue and asking ACLR to "hold off on sending the RFIs for this study until CMS is able to read and review what has been submitted." *Id.* at A597.

204. ACLR responded that "we do recognize the authority of CPI, under Appendix E

(New Issue Submission and Approval Process) Step 5 [of the SOW] to dictate the terms of the actual approval" of the audit issue. *Id.* at A594.

205. CMS then informed ACLR that Livanta, as the data validator, would analyze ACLR's 2010-2012 duplicate payment NAIRP and "apply the approved methodology to ensure that the PDE records that have been identified [by ACLR], should be included in the RFI" sent to the plan sponsors. *Id.* at A594.

206. Livanta reviewed ACLR's potential duplicate payment findings "to determine that the RAC correctly applied the approved methodology in identifying the potential duplicate payments." Tab 113, SA610.

207. Livanta reported to CMS that Livanta questioned thousands of ACLR's potential duplicate payment findings. For instance, Livanta stated that it identified over 13,000 PDE pairs that were coded for vaccination administrative fees, which ACLR had agreed should be excluded from the duplicate payment audit. *Id.* at SA611-612.

208. Livanta also compared the dosages in the PDE record pairs and reported to CMS that, for 2010, 56% of the PDE pairs had a dosage increase from the originating prescription to the potentially duplicative prescription of greater than 50%. *Id.* at SA612.

209. For 2011 and 2012, Livanta reported to CMS that it attempted to perform the same analysis, but the quantity dispensed field in ACLR's data submission had an entry of "zero" in 99% of the PDE records, making the comparison impossible. *Id.*

210. CMS provided Livanta's validation results to ACLR on June 26, 2014, and asked ACLR to "proceed with removing the PDE records that were rejected as a result of the DVC's validation." *Id.* at SA608.

211. ACLR agreed to eliminate the PDEs that were rejected as part of Livanta's

validation work. *Id.*; Tab 90, SA265-66 at 195:20-196:22.

212. Following CMS's review of Livanta's validation report and the concerns raised by Livanta regarding the 2011 and 2012 PDE data contained in ACLR's NAIRP submission, CMS informed ACLR on July 8, 2014, that CMS had approved the release of requests for information to the plan sponsors for the potential duplicate payments identified by ACLR for 2010 only. Tab 52, A618.

213. CMS asked ACLR to advise whether ACLR would "like to move forward with CY 2010 only or if you'd rather wait until you've resolved the issue with the 2011 and 2012 data and send all three plan years at once." *Id.*

214. ACLR responded by blaming Livanta for not identifying the flaws in ACLR's data in previous reviews, but did proceed with preparing the requests for information that were sent to plan sponsors for the 2010 potential duplicate payments identified by ACLR. *Id.*

215. After the requests for information were sent to plan sponsors, the sponsors responsible for more than half of the potential improper payments identified by ACLR contacted CMS to request an extension of time to respond to the requests due to the large volume of PDEs involved. Tab 114, SA619-20.

216. ACLR responded that it was prepared to send out similar requests for information for 2011 and 2012. *Id.* at SA619.

217. CMS reported that it continued to receive more requests for extensions of time to respond to the RFIs for 2010 potential duplicate payments, and that CMS was "working with several plan sponsors to see why there are so many requests for extensions and to try to understand the difficulties they are facing in obtaining and submitting the data requested." Because of those ongoing issues, CMS stated that "it would be difficult for CMS to move

forward with CY 2011 and 2012 without first understanding the issues surrounding CY 2010." *Id.*

218. CMS issued a notice to all plan sponsors on October 1, 2014, notifying them that CMS had extended the deadline for sponsors to respond to the 2010 duplicate payment RFI by 60 days, through December 8, 2014. Tab 53, A620.

219. ACLR sent CMS an email the same day acknowledging that CMS had placed the 2011 and 2012 duplicate payment RFIs "on hold" and had extended the plan sponsor deadline for responding to the 2010 duplicate payment RFI. ACLR stated that it was "not challenging CMS authority with these decisions" but was raising the issues only for consideration in the context of "future SOW changes." Tab 115, SA621-22.

220. CMS met with certain plan sponsors who raised concerns regarding the burdens of responding to ACLR's requests for information and the likelihood that the PDEs identified by ACLR included many false positives. The concern was that many of the PDEs were not, in fact, duplicates at all, requiring the sponsors to submit extensive documentation related to legitimate prescription payments.

221. Some plan sponsors were required by ACLR's notices to produce documentation for thousands of different PDEs at once. One plan sponsor reported to CMS that, to respond to ACLR's 2010 duplicate payment RFI, the plan sponsor would have to generate screen shots for at least 220,000 PDEs, which would take 16 contractors a total of 86 weeks to complete and cost nearly $2 million. Tab 90, SA267-68 at 225:5-226:1; Tab 119, SA630.

222. To attempt to alleviate those concerns, CMS provided ACLR with a revised protocol on October 22, 2014, to be used in analyzing the 2010 PDE records for duplicate payments. Under the revised protocol, CMS requested that ACLR remove from its pool of

potential duplicate payments any PDEs involving a dosage increase of 50% or greater and where the date of service or fill date were different. CMS also asked ACLR to remove any PDE pairs in which the pharmacy or service provider ID and the date of service were different between the two PDE records. *Id.* Tab 56, A643.

223. ACLR ran the revised protocol and determined that it reduced the universe of potential duplicate payments previously identified by ACLR by 66.8%. Tab 116, SA623.

224. Livanta completed a validation of ACLR's revised 2010 duplicate payment analysis, and those results were provided to ACLR on November 13, 2014. Tab 117, SA626.

225. In its validation, Livanta reported, among other things, that more than 2,000 PDE pairs identified by ACLR involved a dosage change and were supposed to be excluded; more than 3,100 PDE pairs involved long-term care prescriptions that were supposed to be excluded; and more than 10,500 PDE records were unpaired, *i.e.*, Livanta could not identify a matching PDE record which would make the records potentially duplicative. *Id.* at SA625-26.

226. CMS asked ACLR to eliminate the PDEs questioned by Livanta by November 14, 2014, so that updated reports identifying the narrower universe of PDEs for which information was sought could be provided to the plan sponsors sufficiently in advance of the existing deadline of December 8, 2014, for the responses to ACLR's outstanding RFI. *Id.* at SA626.

227. ACLR responded to CMS on the same date, stating that the company was "not available to perform this type of work until our return 11/24," because the business was closed due to hunting season. *Id.* at SA625; Tab 90, SA269-70 at 237:1-238:15.

228. ACLR stated that it intended to "dispute each and every finding with the DVC," and recommended to CMS that the agency pursue collection from the plan sponsors of the amounts previously identified by ACLR, without considering or accounting for any of Livanta's

validation concerns. Tab 117, SA626.

229. After the December 8, 2014, deadline passed for plan sponsors to respond to the RFI, ACLR asserts that it reviewed all of the documentation submitted by the plan sponsors and then submitted its final 2010 duplicate payment improper payment review package to CMS on December 24, 2014. Tab 57, A646; Tab 90, SA401 at 242:7-11.

230. The potential duplicate payments identified by ACLR in its improper payment review package were based on the methodology documented in ACLR's May 2014 NAIRP; those findings did not incorporate the revised protocol requested by CMS on October 22, 2014. Tab 90, SA272 at 245:1-20.

231. According to ACLR, it identified duplicate payments occurring in 294 contracts in the total amount of $15,909,550 for 2010. Tab 57, A648; Tab 85, SA146-47.

232. Livanta reviewed ACLR's December 2014 duplicate payment submission and reported that 286,398 of the PDE pairs identified by ACLR "had been previously identified by [Livanta] as dosage change false positives and an additional 50,579 of the pairs were previously identified by [Livanta] as non-dosage change false positives." Tab 118, SA628-29.

233. Livanta also reported that ACLR had failed to provide any explanation or reasoning for why ACLR rejected the information provided by the plan sponsors in response to ACLR's request for information. *Id.* at SA628.

234. CMS asked ACLR to provide Livanta with additional information regarding Livanta's concerns. ACLR declined to do so, instead telling CPI to direct its questions to the CMS contracting officer. *Id.* at SA628-29; Tab 90, SA274-75 at 255:19-256:5.

235. In *ACLR I*, ACLR seeks to recover $2,209,146, which it contends are the contingent fees it would have received if it had been permitted to proceed with the recovery audit

for 2010 potential duplicate payments, and if CMS had, in fact, recovered the entirety of the $15,909,550 in potential duplicate payments that ACLR claims it identified within the 2010 PDE records. Tab 85, SA146-47.

236. That contingent fee is calculated by multiplying the 15% contingency fee rate that was contained in modification 13 to the Part D RAC contract times the first $10 million in ACLR's projection of 2010 duplicate payments, plus the 12% contingency fee rate times the remaining $5,909,550 in ACLR's projection of 2010 duplicate payments. Tab 90, SA294 at 311:3-15.

237. ACLR has no knowledge that CMS actually recovered any, nor all, of that $15.9 million in potential duplicate payments found by ACLR for 2010. *Id.* at SA279 at 273:6-18.

238. ACLR also does not seek to recover any alleged damages in these cases arising out of CMS's decision to place "on hold," and then to cancel, the prior approval of ACLR's NAIRP for potential 2011 and 2012 duplicate payments. *Id.* at SA289-90 at 298:21-299:6.

239. ACLR also asserts in *ACLR I* that it is "entitled to the amount of $2,668,553 representing amounts associated with direct labor costs based on ACLR's approved GSA Schedule rates and contract overhead requirements, reasonable expectations of profit, and net of amounts already collected arising from ACLR efforts during subsequent modifications of the Contract." Tab 85, SA146.

240. ACLR alleges that the $2.6 million figure represents all of ACLR's operating costs and anticipated profit from January 1, 2012, through December 31, 2013, minus the contingent fees that ACLR received from CMS during those years for the other unrelated recovery audit issues that did proceed and for which CMS actually recouped overpayments from plan sponsors. Tab 90, SA251 at 145:3-15, SA252 at 146:8-14, SA279 at 273:19-275:1, SA285

at 284:15-18.

241. ACLR calculated its historical profit rate at 40 to 50 percent, based entirely on its past success performing work in the private sector, not on any Government contracts. Tab 90, SA292-93 at 307:19-308:9.

242. ACLR has not identified any provisions in the contract that provide for payment to ACLR for these types of costs or profit. ACLR agrees that the contract only provides for payment to ACLR in the form of contingent fees calculated off of amounts actually recovered by CMS in response to ACLR's approved audit issues. *Id.* at SA228 at 21:16-23:1, SA235 at 88:5-18; Tab 91, SA298 at 38:15-18, SA299 at 39:13-17, SA302 at 59:11-22, SA305 at 76:12-19.

243. ACLR does not maintain any records tracking actual hours worked by employees on particular issues from which one could verify precisely who worked on which audit issues at any given point in time. Tab 90 at SA283-84 at 279:1-280:17, SA291 at 306:5-15.

244. ACLR has not designated any expert to testify as to this portion of ACLR's alleged damages. Tab 95, SA380-81 at 104:7-105:8.

ACLR's Proposed Audit Issues: Sales Tax Payments

245. ACLR had received the 2012 PDE records from CMS in January 2014, and the 2013 PDE records (as updated) from CMS in June 2015. Tab 91, SA318-19 at 104:21-105:15, SA320 at 106:22-107:3; Tab 86, SA149-50.

246. PDE records contain a field for reporting any "amount attributed to sales tax." Tab 105, SA477.

247. ACLR did not propose conducting a recovery audit for potential improper sales tax payments prior to the submission of its sales tax NAIRP dated August 21, 2015, in which ACLR requested approval for an audit that would look for improper sales tax payments in the

2012 and 2013 PDE records. Tab 61, A663.

248. Prior to the August 2015 NAIRP submission, ACLR had not discussed proposing a sales tax audit with anyone at CMS, no one at CMS had requested that ACLR propose an audit for that issue, and as far as ACLR knows, no one at CMS would have been aware that ACLR even intended to propose a Part D sales tax recovery audit. Tab 91, SA314-17 at 98:18-101:1.

249. ACLR proposed conducting an automated audit, in which it would determine the existence of improper sales tax payments by review of the PDE data alone, without reference to additional supporting documentation or explanations from the plan sponsors. Tab 61, A663.

250. In its NAIRP, ACLR identified for CMS the total amount of the prescription payments for all of the PDEs it had identified as containing data in the sales tax field. *Id.* at A670.

251. According to ACLR, if a PDE erroneously included a single cent in the sales tax field, then the entire PDE payment – including the indisputably correct portions for the drug costs themselves – should be deemed improper and subject to recoupment, not just the erroneous amount of sales tax charged. Tab 91, SA334 at 155:3-9, SA337-38 at 160:22-161:4, SA342 at 201:16-19.

Louisiana

252. Health Integrity, the NBI MEDIC, was asked in September 2014 to conduct an analysis of Louisiana PDE records from January 1, 2010, to August 31, 2014, to determine whether there continued to be a vulnerability related to plan sponsors being paid for sales tax assessments that should not have been imposed on prescriptions within that state. Tab 121, SA638; Tab 123, SA658.

253. Health Integrity concluded, in reports dated October 31 and November 26, 2014,

that during that time period CMS paid approximately 4.3 million PDE records in which some amount greater than $0 was recorded in the sales tax field of the PDE records; the total amount reported in the sales tax field on those PDE records was $922,961.59. Tab 123, SA662.

254. Health Integrity recommended a "state-by-state project study of sales taxes paid under the Medicare Part D Program" to "determine whether the amounts identified in the PDE records as a 'sales tax' actually represent sales taxes in states where the application of sales taxes to Part D prescription drugs is prohibited by law," or if some other legitimate information were being recorded in those PDE fields. *Id.* at SA665.

255. Following receipt of Health Integrity's initial reports on potential sales tax payments in Louisiana, CMS issued an additional notice to Louisiana plan sponsors in December 2014 that informed them that the NBI MEDIC "has determined that your parent organization submitted prescription drug event (PDE) records that included unallowable sales tax payments on Part D prescriptions in Louisiana." CMS directed the plan sponsors to recoup any sales taxes paid on Part D prescriptions in Louisiana and to submit corrected PDE records within 90 days. Tab 134, SA708-09.

256. In February 2015, one Louisiana plan sponsor, Express Scripts, responded to CMS's notice by reporting that, while Louisiana law did not provide for sales taxes on Part D prescriptions, state law *did* require the imposition of a 10¢ fee on all prescriptions, and that that fee was being reported in the PDE sales tax field due to a lack of any other field in which to report the charge. Tab 124, SA671-72.

257. After reviewing the response from Express Scripts, CMS agreed not to pursue recoupment of PDE records containing amounts of 10¢ or less in the sales tax field. *Id.* at SA672.

258. CMS sent a follow-up notice to Louisiana plan sponsors in February 2015, informing them that CMS was continuing to review the issue, and that the plan sponsors need not take further action on recouping the previously identified amounts until further notice. Tab 135, SA711.

259. Health Integrity then conducted a revised analysis where it looked only at amounts greater than 10¢ reported in the sales tax field in Louisiana PDE records between January 1, 2010, and August 31, 2014. That updated analysis revealed that the number of suspect PDEs was reduced from 4.3 million down to 11,578, and the total amount reported in the sales tax field was reduced from $922,961.59 down to only $59,090.36. Tab 124, SA672.

260. Health Integrity updated its analysis again through June 2015, looking at the number of PDE records for the same time period in which amounts greater than 10¢ remained in the universe of records. The total amount reported in the sales tax field in such claims had been reduced further to only $53,125.54, following plan sponsors' correction or deletion of PDE records. For 2012 and 2013, the two years that were the subject of ACLR's proposed sales tax NAIRP submitted on August 21, 2015, Health Integrity reported that there was only $1,789.85 and $18,354.29 reported in the sales tax fields of PDE records, respectively, for PDEs containing amounts greater than 10¢ in that field. Tab 125, SA680-81; Tab 91, SA331 at 144:12-22.

261. ACLR's NAIRP did not address the existence or applicability of the 10¢ Louisiana prescription fee or its potential impact on the viability of ACLR's proposed recovery audit. Tab 91, SA329-30 at 142:14-143:17.

262. Guidance by the Louisiana Department of Insurance states that Louisiana law "authorizes a 10 cent per prescription fee on every out-patient prescription filled by a pharmacy in this state." Tab 136, SA712.

263. The Louisiana Department of Insurance has concluded that the 10¢ fee is not limited only to prescriptions provided to Medicaid enrollees, because "[t]hat argument contradicts the plain language of the statute, its legislative history, and controlling federal law." *Id.* at SA714.

264. The Louisiana Department of Insurance has stated that the statutory 10¢ fee is applied across-the-board to ensure that "all residents of [Louisiana] shoulder the burden of financing the Louisiana Medicaid program." Therefore, the "ten cent provider fee on out-patient prescriptions authorized in [section 46:2625] applies to every out-patient prescription of any kind whatever, without regard to whether that prescription is processed by or for a Medicaid enrollee." *Id.* at SA714-15.

265. ACLR's principal Chris Mucke, who characterizes himself as an "expert on the law," contends that the Louisiana Department of Insurance's interpretation of Louisiana law is incorrect, and that Mr. Mucke's interpretation of Louisiana law should control instead. Tab 95, SA375 at 16:3-16, SA377-79 at 45:20-47:3.

Minnesota

266. On behalf of CMS, Health Integrity also had been analyzing the potential for improper sales tax payments in Minnesota for years before ACLR submitted its sales tax NAIRP in August 2015. In June 2010, following a request for assistance made by the OIG, Health Integrity contacted plan sponsors regarding concerns that sponsors were reporting sales tax in Minnesota PDE records. Tab 127, SA689; Tab 128, SA696; Tab 129, SA701-02.

267. In July 2010, two plan sponsors, UCare and Medica, responded to Health Integrity. UCare noted that "the data in the sales tax field does not represent payment of sales tax, and the reflected payments do not violate state or federal law." Rather, UCare stated that the

payments reported in the PDE sales tax field reflected payments under Minnesota's wholesale drug distributor's tax. Tab 127; Tab 128, SA696.

268. UCare alerted Health Integrity to the existence of the wholesale drug distributor tax and represented that the "data in the sales tax field in UCare's PDE shows the amount of reimbursement for expense of the wholesale drug distributor tax, not a sales tax or a tax on UCare's premium payments from CMS." Tab 128, SA696.

269. UCare also informed Health Integrity that it had sought legal advice from the Minnesota Pharmacists Association and outside counsel, both of which advised UCare that "the federal law prohibiting taxes and assessments would likely not be construed by a court to preempt our obligation under state law to reimburse pharmacies for the expense of the wholesale drug distributor tax." *Id.* at SA697.

270. UCare obtained an email from a regional CMS official who advised that "this tax survives the . . . federal provision" preempting state imposition of premium taxes or fees on Medicare Part D payments. *Id.*

271. Medica likewise informed Health Integrity that "the tax associated with the PDE data for the claims at issue represents a wholesale drug distributor tax," not sales tax, and thus was allowed under state law. Tab 127, SA689.

272. Health Integrity contacted the Minnesota Attorney General's office to obtain further guidance on the issue. A "citizen research specialist" responded to Health Integrity by letter dated May 31, 2011, noting the existence of the wholesale distributor tax but providing a contrary opinion that "healthcare services provided to Medicare recipients and paid for under the Medicare program are exempt from this tax." Tab 137, SA717.

273. Ultimately, Health Integrity prepared an executive summary regarding its analysis

of the Minnesota tax issues. Tab 129, SA701.

274. The issue of the applicability of the Minnesota wholesale drug distributor tax to Part D prescriptions apparently remained open and unresolved, and CMS asked Health Integrity to analyze the issue again in 2014. Tab 122, SA647.

275. In a report dated November 3, 2014, Health Integrity informed CMS that it had analyzed Minnesota PDEs between January 1, 2010, and September 30, 2014, and identified a total of 62.6 million PDEs containing amounts reported in the sales tax field, with amounts totaling $90,928,414 reported in the sales tax field. *Id.* at SA652-53.

276. Health Integrity recommended a more detailed analysis to specifically include "whether the amounts identified in the PDE records as a 'sales tax' actually represent sales taxes in states where the application of sales taxes to Part D prescription drugs is prohibited by state law." *Id.* at SA655.

277. CMS and Health Integrity discussed Minnesota tax issues throughout 2015, and CMS informed Health Integrity that CMS wanted to complete the analysis of Louisiana taxes before proceeding with any further vulnerability analysis in Minnesota. Tab 139, SA743.

278. Health Integrity reported that, if one accounted for the 2% wholesale drug distributor tax, the $90.9 million total amount reported in the sales tax field for Minnesota PDEs from 2010 through 2014 would be reduced to $10.2 million. *Id.*

279. Health Integrity noted that the "Sales Tax Field is being used for other items," which might be a "vulnerability that we will need to review further after we settle the sales tax cases." *Id.*

280. [redacted]

[redacted]. Tab 93, SA366-68 at 126:5-128:15; Tab 97, SA392-94 at 91:3-93:15, SA395-96 at 133:14-134:2, SA397-98 at 141:22-142:7; Tab 98, SA410-11 at 50:22-51:16.

281. ACLR's NAIRP did not address the applicability of the wholesale drug distributor fee or its potential impact on the viability of ACLR's proposed recovery audit of alleged sales tax payments in Minnesota in any way. Tab 91, SA339 at 170:2-6.

Other States

282. CMS requested that Health Integrity conduct a nationwide study of amounts reported in the sales tax field. Tab 124, SA668, SA673-75.

283. In its review, Health Integrity observed that "aberrant patterns were identified concerning the monetary information that is being populated within the sales tax field." In some cases Health Integrity determined that plan sponsors were recording usage taxes in the sales tax field, but "there were a large number of instances in which the sales tax field bore no discernable relationship to the remainder of the PDE record." *Id.* at SA668.

284. Health Integrity's national study looked at PDE records for 2014, and found that 3.38% of the PDE records in that year (47.9 million out of 1.4 billion total PDE records) contained amounts recorded in the sales tax field. *Id.* at SA673.

285. Illinois was the only state identified by Health Integrity as imposing a sales tax (as opposed to some other form of tax or fee) on prescription drugs. *Id.*

286. In the top 15 states with amounts reported in the sales tax fields of the PDE records, Health Integrity identified a total of $66 million in payments reported in the sales tax fields. *Id.* at SA674. Of those same top 15 states, $38.9 million out of the total $66 million (59%) came from PDE records in Illinois (which does impose sales taxes on prescriptions), and

$24.7 million out of the total $66 million (37.4%) came from Minnesota. *Id.* at SA674.

287. Health Integrity identified the sales tax field as a vulnerability that CMS should consider addressing through further guidance to plan sponsors, to clarify the purposes for which the sales tax field could be used. *Id.* at SA675.

288. Health Integrity's national vulnerability study remained open until December 23, 2015, and at that time Health Integrity's "findings remain[ed] under review by CMS for further action." Tab 126, SA683, SA686. As of January 29, 2016, Health Integrity reported that its findings still remained under review by CMS. *Id.* at SA688.

289. Due to the complexity of the issues, CMS has not further pursued the recovery of any amounts reported in the sales tax fields of PDE records that might amount to improper assessments of state sales taxes. Tab 101, SA426 at 56:12-18, 59:8-15; Tab 98, SA412 at 97:5-11; Tab 97, SA399 at 230:12-15, SA400-01 at 241:18-242:12.

290. CMS's view was that, if an amount reported in the sales tax field on a PDE record reflected an allowable payment for some form of tax or fee – even if not actually state sales tax – then it would not be deemed an improper payment merely because the payment was recorded in the sales tax field. Tab 97, SA390-91 at 86:8-87:1.

291. In the notice denying ACLR's proposed sales tax NAIRP, the CMS contracting officer's representative invited ACLR to contact her with any questions regarding the denial of the NAIRP, but ACLR never considered doing so. Tab 62, A672; Tab 91, SA341 at 191:10-15.

292. ACLR submitted a certified claim a week after the sales tax NAIRP was denied, alleging that it was entitled to payment of its contractual contingency fee as if the sales tax recovery audit had been approved and CMS had recouped the entirety of the PDE payments – not just the alleged sales tax amounts – contained in the PDEs identified in ACLR's NAIRP.

Tab 86, SA152; Tab 91, SA342 at 201:16-19.

293. ACLR had identified $658,354,795 in total PDE payments on the records it identified in its NAIRP as containing some amount in the sales tax field. ACLR computed its contingent fee by multiplying the contractual 15% contingent fee rate times the first $10 million in hypothetical recoveries, and then multiplying the 12% contractual contingent fee rate times the remaining $648,354,795 in hypothetical recoveries, to arrive at a total alleged entitlement of $79,302,575. Tab 61, A670; Tab 86, SA152; Tab 91, SA342-43 at 201:22-202:19.

294. ACLR has no evidence that CMS ever recovered any, nor all, of the amounts identified as improper sales tax payments in ACLR's NAIRP. Tab 91, SA346-47 at 211:8-212:7.

295. ACLR's complaint in *ACLR II* is based on the same categories of PDEs containing alleged improper sales tax payments that were identified in its sales tax NAIRP and certified claim, but asserts that there are millions of additional PDEs and millions of additional dollars of PDE payments containing alleged sales tax amounts than had ever previously been identified by ACLR to CMS. Tab 91, SA348-49 at 218:5-219:16.

296. For instance, ACLR's NAIRP and certified claim asserted that ACLR had identified 27,272,409 Minnesota PDEs containing amounts in the sales tax field with total PDE payments on those claims equaling $619,184,285. Yet ACLR's complaint alleges that it found 38,145,596 Minnesota PDEs containing amounts in the sales tax field with total PDE payments equaling $889,596,525 – an increase of roughly 11 million PDEs and $270 million in total PDE payments. Tab 61, A670; Tab 87, SA156 at ¶ 18; Tab 91, SA348-49 at 218:5-219:16.

297. ACLR's complaint also alleges that it found 2,045,929 Louisiana PDEs containing amounts in the sales tax field with total PDE payments equaling $32,032,166 – an

increase of roughly 230 PDEs and $4,000 in total PDE payments compared to what had been reported to CMS in the NAIRP and sought in ACLR's certified claim. Tab 87, SA156 at ¶ 23; Tab 61, A670; Tab 91, SA349-50 at 219:17-220:17.

298. ACLR's complaint alleges that it identified 264,119 PDEs that contained amounts in the sales tax field that were greater than 50% of the reported drug costs with total PDE payments on those claims equaling $2,009,005 – an increase of roughly 2,000 PDEs and $400,000 compared to what ACLR reported in its NAIRP and sought in its certified claim. Tab 87, SA157 at ¶ 28; Tab 61, A670; Tab 91, SA350-51 at 220:18-221:12.

299. ACLR's certified claim was based on the PDE data reported in ACLR's sales tax NAIRP. Tab 91, SA351 at 221:13-21.

300. ACLR never discussed with CMS the additional 2012 and 2013 PDE records and payments that it alleges in its complaint, that go above and beyond the records referenced in the NAIRP, nor did ACLR seek a contracting officer's final decision involving the revised claim data. *Id.* at SA351-52 at 221:22-222:11.

301. The new claims identified in ACLR's complaint are different prescriptions that had not been identified by ACLR for CMS at any time prior to filing the complaint. *Id.* at SA354-55 at 226:-227:14-18.

302. Based on the new increased number of PDEs and total PDE payments that ACLR contends were improper, ACLR's complaint now seeks contingent fees of $112,002,489 (rather than the $79,302,575 asserted in the certified claim) calculated off of the total dollar amount of the PDEs identified by ACLR in which any amount was included in the sales tax field. Tab 91, SA356 at 230:12-19.

303. ACLR's principal, Chris Mucke, is the only individual who performed any work

on the sales tax NAIRP and the analysis of state taxation laws. He estimates that it took no more than a few days of work to analyze the PDEs to generate ACLR's proposed sales tax NAIRP and to analyze state laws to determine the applicability of sales taxes to Part D prescriptions. Tab 91, SA322 at 109:10-14, SA323 at 111:12-16, SA327-28 at 120:21-121:14.

General Recovery Audit Matters

304. Guidance issued by OMB states that "[c]ontingency fee contracts shall preclude any payment to the payment recapture audit contractor until the recoveries are actually collected by the agency." . Similarly, OMB's guidance provides that "[o]verpayments that are identified by the payment recapture auditor, but that are subsequently determined not to be collectable or not to be improper, shall not be considered 'collected' for proceed disposition purposes outlined in this section." Tab 89, SA207-08.

305. OMB's guidance also provides:

> When calculating a program's annual improper payment amount, agencies should only utilize the amount paid improperly. For example, if a $100 payment was due, but a $110 payment was made erroneously, then the amount applied to the annual estimated improper payment amount should be $10, rather than the payment amount of $110. Similarly, if a $100 payment was due, but a $90 payment was made erroneously, then the amount applied to the annual estimated improper payment amount should be $10, rather than the payment amount of $90. However, if a $100 payment was due and made, but there is insufficient documentation to support the appropriateness of the payment or if a duplicate payment was made, then the amount applied to the annual estimated improper payment amount should be $100.

Tab 89, SA182-83.

306. ACLR stated that the ultimate recovery on any of its audit issues was always less than what it projected at the beginning, and in some cases varied "significantly" compared to the amounts estimated at the audit's outset. Tab 91, SA307 at 81:5-13, SA308 at 82:4-9, SA344 at

207:8-18.

307. ACLR never expected that it could achieve a 100% success rate in recovering overpayments. Tab 91, SA301 at 48:8-13.

308. GAO determined that the rate of recovery on several Part D audit issues completed by ACLR ranged from 22% to 99%, when comparing the estimated improper payments identified by ACLR with the amounts actually recovered by CMS. Tab 15, A321; Tab 91, SA312 at 93:2-19.

309. According to ACLR, in certain instances one cannot determine, from the PDE records alone, whether a Part D payment is proper or improper. Tab 91, SA313 at 97:17-22.

310. ACLR's owner, Chris Mucke, testified that he anticipated being "retired and living on an island anywhere" after having "received hundreds of millions back in improper payments" as a result of this contract. Tab 90, SA282 at 278:5-9.

Respectfully submitted,

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